

EXHIBIT 41

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**[PROPOSED] ORDER DENYING
DEFENDANTS MALLINCKRODT ARD
LLC AND MALLINCKRODT PLC'S
MOTION TO STRIKE**

Judge: Hon. Stephen Kaus

Location: Dept. 19

Hearing: August 5, 2020; 3:00 p.m.

Complaint Filed: February 27, 2020

Trial Date: Not Set

1 Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (together, “Mallinckrodt”), moved
 2 to strike certain allegations from the complaint of plaintiff Health Care Services Corporation
 3 (“HCSC”), filed on February 27, 2020. Being fully advised in the matter and good cause appearing,
 4 Mallinckrodt’s motion to strike is DENIED.

5 Mallinckrodt’s motion to strike improperly asks the Court to strike relevant allegations that
 6 Mallinckrodt contends do not constitute a cause of action. A “motion to strike does not lie to attack a
 7 complaint for insufficiency of allegations to justify relief; that is a ground for general demurrer.”
 8 *Pierson v. Sharp Mem’l Hosp.*, 216 Cal. App. 3d 340, 342–43 (1989).

9 Along with their demurrer, Mallinckrodt challenges the sufficiency of HCSC’s allegations by a
 10 motion to strike, but a motion to strike “is not the proper method of attacking a pleading which is
 11 merely insufficient to state a cause of action, or defense, or which is defective in form.” *Allerton v.*
 12 *King*, 96 Cal. App. 230, 233 (1929). Under Cal. Civ. Proc. Code § 436(a), any “matter that is essential
 13 to a cause of action should not be struck and it is error to do so.” *Quiroz v. Seventh Ave. Ctr.*, 140 Cal.
 14 App. 4th 1256, 1281 (2006). An argument that a complaint did not state facts sufficient to constitute a
 15 cause of action is ground for demurrer and is not, therefore, a proper ground for a motion to strike.
 16 *Ferraro v. Camarlinghi*, 161 Cal. App. 4th 509 (2008). Thus, allegations of wrongdoing such as would
 17 demonstrate knowledge, scienter, or a consistent behavioral practice remain relevant and should not
 18 be stricken, even if some of the alleged conduct occurred outside the limitations period. *Alch v.*
 19 *Superior Court*, 122 Cal. App. 4th 339, 374 n.30 (2004) (“consideration of the entire scope of a hostile
 20 work environment claim, including behavior alleged outside the statutory time period, is permissible
 21 for the purposes of assessing liability, so long as any act contributing to that hostile environment takes
 22 place within the statutory time period.”) (quoting *AMTRAK v. Morgan*, 536 U.S. 101, 113 (2002)).
 23 Mallinckrodt’s use of a motion to strike is improper in three ways.

24 First, Mallinckrodt requests that the Court strike a multitude of factual allegations in the
 25 complaint that support otherwise valid causes of action. including: Complaint, ¶¶ 11, 76-85
 26 (Mallinckrodt has a vertically integrated distribution system); ¶¶ 12, 89-120, 273-75, 281, 323
 27 (Mallinckrodt’s co-pay funds were fraudulent); ¶¶ 14, 149-61, 181, 257, 272-273 (Mallinckrodt
 28 funneled kickbacks to prescribing doctors); ¶¶ 13, 121-48 (Mallinckrodt promoted Acthar off-label);

¶¶ 15, 162-76, 200, 203, 244-47, 249-53 (Mallinckrodt acquired and killed Synacthen). This is improper. Mallinckrodt fails to show that any of the individual paragraphs are irrelevant, false or improper; if the Court overrules Mallinckrodt's demurrer *a fortiori* they cannot be any of these things. A motion to strike is not a "line item veto." *PH II, Inc. v. Superior Court*, 33 Cal. App. 4th 1680, 1683 (1995).

Second, Mallinckrodt moves to strike allegations regarding its settlement with the DOJ to resolve claims the company paid illegal kickbacks to physicians (Complaint, ¶ 161) and allegations regarding Mallinckrodt's settlement with the FTC of charges that it violated antitrust laws in its acquisition of an Acthar competitor (¶ 175). The FTC and DOJ settlements are relevant to HCSC's antitrust claims. *See, e.g., In re Nat'l Ass'n of Music Merchants, Musical Instruments & Equip. Antitrust Litig.*, 2011 WL 3702453, at *2 (S.D. Cal. Aug. 22, 2011) (denying motion to strike references to FTC complaint). At minimum, facts developed in the FTC and DOJ matters will frame, in part, the scope of the factual and legal issues to be resolved here, and the actions taken help inform statute of limitations issues.

Third, Mallinckrodt seeks to have the court strike HCSC's state law claims for relief based on supposed legal deficiencies (Complaint, ¶¶ 245, 253, 257,¹ and 280). Just as with the factual allegations above, the proper mechanism for challenging the legal sufficiency of these allegations is through a demurrer, not a motion to strike. And these paragraphs are necessary to describe the legal grounds under which HCSC is entitled to relief. Mallinckrodt's motion is without merit and is denied.

Dated: _____, 2020

IT IS SO ORDERED.

Hon. Stephen Krause
Judge of the Superior Court

Submitted by:

¹ Mallinckrodt incorrectly cites paragraph 245 in its motion to strike.

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EXHIBIT 42

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

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Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**[PROPOSED] ORDER GRANTING
PLAINTIFF HEALTH CARE SERVICE
CORP.'S REQUEST FOR JUDICIAL
NOTICE IN SUPPORT OF
OPPOSITION TO DEFENDANTS
MALLINCKRODT ARD LLC AND
MALLINCKRODT PLC'S DEMURRER
AND MOTION TO STRIKE**

Judge: Hon. Stephen Kaus

Location: Dept. 19

Hearing: August 5, 2020; 3:00 p.m.

Complaint Filed: February 27, 2020

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1 **I. INTRODUCTION**

2 Pursuant to Cal. Evid. Code §§ 451-53, Plaintiff Health Care Services Corporation (“HCSC”) requested that the Court take judicial notice of the following documents in support of HCSC’s
3
4 Opposition to Defendant Mallinckrodt ARD LLC and Mallinckrodt plc’s Demurrer and Motion to Strike: (1) Order, *United States of America ex rel. Strunck*, No. 12-cv-0175 (E.D. Pa. Mar. 8, 2019), RJN
5 Exhibit 1; (2) Complaint in intervention filed by the U.S. Department of Justice in *United States of America ex rel. Strunck*, No. 12-cv-0175 (E.D. Pa. June 4, 2019), RJN Exhibit 2; and (3) a press release
6
7 by the United States Department of Justice (“DOJ”), “United States Intervenes in False Claims Act Lawsuit Against Drug Maker Mallinckrodt Alleging Illegal Kickbacks,” June 5, 2019, RJN Exhibit 3.¹
8
9 HCSC’s request for judicial notice is GRANTED for the reasons that follow.
10

11 **II. ANALYSIS**

12 This Court may take judicial notice of “[r]ecords of (1) any court of this state or (2) any court of record of the United States or of any state of the United States.” Evid. Code § 452(d). Exhibits 1
13
14 and 2 are such court records noticeable under this rule because they are a court order issued by the United States District Court for the Eastern District of Pennsylvania, and a complaint filed in the
15
16 same court by the U.S. Department of Justice (“DOJ”). These documents are subject to mandatory judicial notice as (1) HCSC’s filing served sufficient notice to Mallinckrodt, and (2) the true and
17
18 accurate copies attached provided sufficient information to the Court to satisfy Evidence Code § 453.

19 This Court may take judicial notice of “[o]fficial acts of the . . . executive . . . departments of the United States.” Evid. Code § 452(c). Exhibit 3 is such an executive record noticeable under this
20
21 rule because it explains and announces action taken by the U.S. DOJ. *Licudine v. Cedars-Sinai Med. Ctr.*, 3 Cal. App. 5th 881, 902 (2016) (“[W]e can take judicial notice of official acts and public records.”).²
22
23 Exhibit 2, which is the U.S. DOJ’s complaint in intervention, similarly reflects “official acts” of the
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26 ¹ These documents were attached as Exhibits 1 through 3 to the Declaration of Matthew S. Weiler, and are thereby authenticated.

27 ² The comments by the Assembly Committee on Judiciary to Evid. Code § 452(c) note: “Under this provision, the California courts have taken judicial notice of a wide variety of administrative and
28 executive acts, such as proceedings and reports”

1 United States. These acts are subject to mandatory judicial notice as (1) HCSC's filing served as
 2 sufficient notice to Mallinckrodt, and (2) the true and accurate copies (and the internet addresses listed
 3 above) provided sufficient information to the Court to satisfy Evid. Code § 453.

4 Exhibits 1 through 3 should be judicially noticed because they provide the dates of publication
 5 of actions taken by the DOJ, including the filing of a complaint that publicly disclosed wrongdoing.
 6 The date of publication is relevant to refuting claims made by Mallinckrodt that HCSC's claims are
 7 time-barred. *See Trinity Park, L.P. v. City of Sunnyvale*, 193 Cal. App. 4th 1014, 1045 (2011),
 8 disapproved on other grounds, *Sterling Park, L.P. v. City of Palo Alto*, 57 Cal. 4th 1193, 1210 (2013).
 9 Dates of documents reflecting acts such as issuing an order or filing a complaint may be judicially
 10 noticed under Section 452(c) of the Evidence Code. *See Cabill v. San Diego Gas & Elec. Co.*, 194 Cal.
 11 App. 4th 939, 950 (2011) ("we hereby grant Owners' February 1, 2011, motion for judicial notice and
 12 take judicial notice of the certificate issued on January 27, 2011, by the Secretary of State.").

13 The date that a *qui tam* complaint is unsealed or published can provide relevant dates for
 14 purposes of statute of limitations, even when Defendants argue that the wrongdoing should have
 15 been discovered earlier. *See Williams v. Countrywide Fin. Corp.*, No. 2:16-cv-04166-CAS (AGRx), 2017
 16 U.S. Dist. LEXIS 36495, at *21 (C.D. Cal. Mar. 13, 2017) ("As relevant here, plaintiffs allege that they
 17 first became aware that their appraisals were fraudulent on May 13, 2012, when the Lagow complaint
 18 alleging misconduct by LandSafe was first unsealed."); *Int'l Union of Operating Eng'rs, Stationary Eng'rs*
 19 *Local 39 Pension Tr. Fund v. Bank of N.Y. Mellon Corp.*, No. C 11-03620 WHA, 2012 U.S. Dist. LEXIS
 20 18281, at *21 (N.D. Cal. Feb. 14, 2012) ("Plaintiff pleads sufficient facts to establish equitable tolling
 21 of the statutes of limitation. Plaintiff alleges that it was unaware of defendants' 'deceptive practices'
 22 until the recent unsealing of several whistleblower complaints filed by defendants' employees.
 23 Nothing in the FX rates reported to plaintiff indicated that the rates were false and included hidden
 24 and unauthorized markups or markdowns").

25 **III. CONCLUSION**

26 HCSC's request for judicial notice is GRANTED. HCSC has established the following facts:

- 27 • The operative complaint in the *qui tam* action, *United States of America ex rel. Strunck*,
 28 was ordered unsealed on March 8, 2019. Exhibit 1;

- The U.S. DOJ filed its own complaint in intervention on or about June 4, 2019 in the *Strunck* action. Exhibit 2; and
- The U.S. DOJ publicized the existence of the *qui tam* actions on June 5, 2019. Exhibit 3.

Dated: _____, 2020

IT IS SO ORDERED.

Hon. Stephen Krause
Judge of the Superior Court

Submitted by:

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EXHIBIT 43

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
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HEALTH CARE SERVICE CORP.,

Plaintiff,

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MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**[PROPOSED] ORDER OVERRULING
DEFENDANTS MALLINCKRODT ARD
LLC AND MALLINCKRODT PLC'S
DEMURRER**

Judge: Hon. Stephen Kaus

Location: Dept. 19

Hearing: August 5, 2020; 3:00 p.m.

Complaint Filed: February 27, 2020

Trial Date: Not Set

1 **I. Introduction**

2 Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (together, “Mallinckrodt”),
3 demurred to the complaint of plaintiff Health Care Services Corporation (“HCSC”), filed on February
4 27, 2020. Being fully advised in the matter and good cause appearing, Mallinckrodt’s demurrer is
5 OVERRULED, for the reasons that follow.

6 HCSC’s claims relate to H.P. Acthar Gel (“Acthar”), a critical prescription drug used to treat
7 infant seizures. Although Acthar had been available in the United States since 1952, it has seen some
8 of the largest price hikes in the history of medicine, increasing nearly ten thousand-fold from 2001 to
9 2018. To pull this off, Mallinckrodt allegedly acquired the rights to Acthar, and subsequently (i)
10 eliminated competition in the market for Acthar through an exclusive distribution agreement; (ii)
11 completed a “catch and kill” acquisition of Acthar’s only biologically equivalent competitors; and (iii)
12 created artificial demand for Acthar by illegally subsidizing patient co-payments, promoting off-label
13 use of the drug, and bribing physicians to prescribe it. As a result of Mallinckrodt’s allegedly
14 anticompetitive and fraudulent conduct, HCSC alleges that it has paid millions of dollars more for
15 Acthar than it otherwise would have.

16 HCSC alleges claims for violations of New Jersey’s Racketeer Influenced Corrupt
17 Organizations Act (Counts I & II), antitrust violations (Counts III & IV), unfair and deceptive trade
18 practices (Count V), fraud (Count VI), insurance fraud (Count VII), tortious interference with
19 contract (Count VIII), and unjust enrichment (Count IX).

20 **II. Legal Standard on Demurrer**

21 “As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are
22 deemed to be true, however improbable they may be.” *Del E. Webb Corp. v. Structural Materials Co.*, 123
23 Cal.App.3d 593, 604 (1981). “[A]ll material facts pleaded in the complaint and those that arise by
24 reasonable implication . . . are deemed admitted by the demurring party. The complaint must be
25 construed liberally by drawing reasonable inferences from the facts pleaded.” *Rodas v. Spiegel*, 87
26 Cal.App.4th 513, 517 (2001) (citation omitted). “A complaint’s allegations are construed liberally in
27 favor of the pleader.” *Ferrick v. Santa Clara Univ.*, 231 Cal. App. 4th 1337, 1341 (2014); Cal. Code Civ.
28 Proc. § 452.

1 Mallinckrodt contends “plausibility” is the standard that governs HCSC’s allegations. MPA at
 2 17, 24, 25, 31. This is error. California pleading practice does not require that allegations be
 3 “plausible.” *See, e.g., Del E. Webb Corp.*, 123 Cal. App. 3d at 604 (“As a general rule in testing a pleading
 4 against a demurrer the facts alleged in the pleading are deemed to be true, however improbable they
 5 may be.”); Weil & Brown, et al., CALIFORNIA PRACTICE GUIDE: CIVIL PROCEDURE
 6 BEFORE TRIAL ¶ 7:44 (2015).

7 **III. Analysis**

8 **A. HCSC Sufficiently Alleges Violations of State Antitrust Law.**

9 HCSC alleges that Mallinckrodt overpaid for and then shelved the exclusive licensing rights to
 10 Synacthen, the only potential competition to Acthar in the United States ACTH market. Mallinckrodt
 11 does not dispute that this conduct amounts to an unlawful restraint of trade or monopoly in violation
 12 of the antitrust laws. Indeed, in *City of Rockford*, the court found that “[o]ne can plausibly infer that the
 13 Synacthen Acquisition and Mallinckrodt’s immediate ‘shelving’ of Synacthen had no legitimate
 14 business justification and resulted in the maintenance and entrenchment of Mallinckrodt’s
 15 monopoly.” *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 757 (N.D. Ill. 2019).

16 HCSC alleges that Mallinckrodt entered into an exclusive distribution agreement with Express
 17 Scripts to maintain Mallinckrodt’s monopoly in the ACTH market. This arrangement foreclosed
 18 competition in the ACTH market to the detriment of consumers. This conduct is part of
 19 Mallinckrodt’s scheme to monopolize the ACTH market in violation of state law equivalents to
 20 Section 1 and 2 of the Sherman Act.

21 Mallinckrodt attacks HCSC’s theories by arguing (i) ACTH is not a relevant antitrust market,
 22 (ii) that HCSC was uninjured, and (iii) HCSC’s exclusive distribution allegations state no claim.

23 **1. Mallinckrodt’s Conduct Impacted a Relevant Antitrust Market.**

24 Mallinckrodt argues that HCSC has failed to allege a proper antitrust market because “Acthar
 25 represents 100% of the [ACTH] market” and HCSC also alleges that non-ACTH drugs are *medical*
 26 substitutes for the treatment of many Acthar indications. Mallinckrodt’s arguments ignore a great
 27
 28

1 body of relevant case law that define relevant antitrust markets in the pharmaceutical context as a
 2 brand drug and its biological equivalent.

3 A “relevant market” is properly defined as consisting of “commodities reasonably
 4 interchangeable by consumers for the same purposes.” *United States v. E.I. du Pont de Nemours & Co.*,
 5 351 U.S. 377, 395 (1956). “The Supreme Court has held that a properly constituted market may
 6 indeed be comprised of a single product ... and lower courts across the country have on numerous
 7 occasions ruled that both a brand-name drug and its generic analogs can fall within the bounds of a
 8 relevant market.” *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 388 (D. Mass. 2013)
 9 (collecting cases showing the market consists of a brand drug and a generic substitute). In other
 10 words, ACTH and its biological equivalents (e.g. Synacthen) is a proper antitrust market.

11 Here, HCSC alleges that there are no economic substitutes for Acthar, other than a biological
 12 equivalent ACTH. HCSC’s allegations give boundaries to the market commonly accepted in
 13 pharmaceutical antitrust litigation: it is ACTH and its biological equivalent, as no other drug could
 14 take away sales anywhere close to as much as a generic could have done. *See In re Cipro Cases I & II*, 61
 15 Cal. 4th 116, 157 (2015) (relevant market under the Cartwright Act is a brand drug and its generic
 16 substitute).

17 Mallinckrodt posits that some other treatments may offer similar therapeutic relief. What’s
 18 missing from this analysis is that the other treatment are **not** biological equivalents. *Cf. United Food &*
 19 *Commer. Workers Local 1776 v. Teikoku Pharma USA*, 296 F.Supp.3d 1142, 1172 (N.D. Cal.
 20 2017) (“something *more* than mere therapeutic equivalency is required to define the relevant antitrust
 21 product market.”). In any event, the definition of the market at issue is a question of fact, not properly
 22 resolved on a demurrer. *See Loestrin*, 261 F.Supp.3d at 326 (“courts generally treat this fact-intensive
 23 issue as one to be decided on a motion for summary judgment (if no genuine issue of material fact
 24 exists) or at trial.”); *Flovac, Inc. v. Airvac, Inc.*, 817 F.3d 849, 853 (1st Cir. 2016) (“The definition of the
 25 relevant market is ordinarily a question of fact”); *Nexium*, 968 F.Supp.2d at 388 n.19 (“the reasonable
 26 interchangeability of brand Nexium with other drugs” is “a factually intensive determination [that] is
 27 better left for resolution by a jury”).

28

1 Mallinckrodt points to the *Humana* decision where the court dismissed with leave to amend
 2 antitrust claims based on an ACTH-only market. However, the *Humana* court did not consider the
 3 *economic* substitutability of other products with Acthar, did not address the line of cases cited above,
 4 and did not consider well-pled allegations of biological equivalents and relative cross-elasticity, which
 5 demonstrate that only biological equivalents could take significant market share away from Acthar. *See*
 6 *Humana Inc. v. Mallinckrodt ARD, LLC*, No. CV-19-06296, 2020 U.S. Dist. LEXIS 101378, at **7–19
 7 (C.D. Cal. Mar. 9, 2020).

8 **2. The Synacthen Acquisition Caused HCSC Injury.**

9 Mallinckrodt contends that HCSC “fails to offer ‘specific facts’ making th[e] connection
 10 between the [Synacthen acquisition] and injury plausible[.]” This argument ignores HCSC’s
 11 allegations. HCSC alleges that three firms negotiated for the rights to license Synacthen, a lower-
 12 priced Acthar alternative. The firms planned to develop Synacthen to compete with, and price below,
 13 Acthar. The firms had the requisite expertise, financing, business, and regulatory plans to develop
 14 Synacthen for the United States market. Had Mallinckrodt not swept in at the eleventh hour with an
 15 outsize bid, another company would have “begun manufacturing Synacthen shortly after acquiring the
 16 license from Novartis and launched the product earlier than Mallinckrodt.” This course of conduct
 17 enabled Mallinckrodt to prevent entry of Synacthen into the United States market, raise the price of
 18 Acthar, and maintain its monopoly power in the ACTH market. And “but for Mallinckrodt’s
 19 monopolistic conduct, including its acquisition of Synacthen, HCSC would have benefitted from
 20 increased competition in the market for ACTH drugs and would have either paid lower prices for
 21 Acthar or steered its members to lower priced Synacthen.” These allegations clearly allege that
 22 Mallinckrodt’s acquisition of Synacthen and its subsequent shelving caused HCSC injury. No more is
 23 needed.

24 Mallinckrodt’s contention that HCSC failed to allege “when Synacthen would have gone
 25 through the extensive clinical trials to establish its safety and efficacy necessary to gain FDA approval
 26 an[d] enter the market” and “which indications FDA would approve it for,” ignores HCSC’s
 27 allegations. HCSC alleges the when, and it is reasonable to infer that another company would have
 28 sought approval of Synacthen for the same indications as Acthar. *See Rodas v. Spiegel*, 87 Cal.App.4th

1 513, 517 (2001) (when ruling on a demurrer, courts are to construe complaints “liberally by drawing
2 reasonable inferences from the facts pleaded.”)

3 3. HCSC’s Allegations of Exclusive Distribution Are Actionable.

4 Mallinckrodt argues that one aspect of HCSC’s allegations—that HCSC was able to maintain
5 inflated prices through an exclusive distribution agreement through Express Scripts—fails to state a
6 claim. Mallinckrodt misconstrues HCSC’s allegations, which do not exist in a vacuum. Mallinckrodt
7 improperly considers the exclusive distribution agreements in isolation, which is fatal to its challenge
8 because “in the antitrust context, the ‘character and effect of a conspiracy are not to be judged by
9 dismembering it and viewing its separate parts, but only by looking at it as a whole.’ ” *Costco Wholesale*
10 *Corp. v. Maleng*, 522 F.3d 874, 886 (9th Cir. 2008) (quoting *Continental Ore Co. v. Union Carbide & Carbon*
11 *Corp.*, 370 U.S. 690, 699 (1962)). A wholistic view is also applied to monopolization claims. *See Med.*
12 *Res. Corp. v. Ethicon Inc.*, 2006 U.S. Dist. LEXIS 12845, at *17 (C.D. Cal. Feb. 2, 2006) (in determining
13 willfulness, “what is dispositive is the overall effect of the conduct”); *Mishawaka v. Am. Elec. Power Co.*,
14 616 F.2d 976, 986 (7th Cir. 1980) (“[Defendant] would have us consider each separate aspect of its
15 conduct separately and in a vacuum. If we did, we might agree with the utility that no one aspect
16 standing alone is illegal. It is the mix of the various ingredients of utility behavior in a monopoly broth
17 that produces the unsavory flavor.”).

18 While exclusive distribution arrangements are “not illegal **in themselves**,” they can run afoul
19 of antitrust laws as “an improper means of maintaining a monopoly.” *See United States v. Dentsply Int’l,*
20 *Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) (emphasis added). Such arrangements violate the antitrust laws
21 when they “foreclose competition in a substantial share of the line of commerce affected.” *Allied*
22 *Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 996 (9th Cir. 2010). In other
23 words, the arrangements are unlawful when they “harm the competitive process, and thereby harm
24 consumers.” *McWane, Inc. v. FTC*, 783 F.3d 814, 835–36 (11th Cir. 2015).

25 HCSC sufficiently alleges that the challenged arrangement has completely foreclosed
26 competition in the ACTH market. The exclusive arrangement foreclosed other distributors from
27 competing with Express Scripts, meaning there is no competition for the downstream sales to
28 consumers. By engaging with only Express Scripts, Mallinckrodt has restricted patient access to

1 Acthar and “eliminat[ed] other distributors from negotiating for lower prices for Acthar.” *Rockford*,
 2 360 F.Supp.3d at 744 (determining that plaintiffs sufficiently allege competitive harm flowing from
 3 Mallinckrodt’s exclusive dealing arrangement). Here, as in *Rockford*, “Express Scripts had no interest in
 4 lowering the price for Acthar because it was making money off all aspects of its exclusive arrangement
 5 with the manufacturer.” *Id.* at 744–45. The arrangement “thus allowed Mallinckrodt to maintain its
 6 dominant monopoly power in the ACTH drug market, maintain prices at artificially high levels, and
 7 exclude less expensive competitive products from the ACTH drug market.” *Id.* at 755.

8 Mallinckrodt argues that an exclusive distribution arrangement “provides no monopolistic
 9 benefit to [a monopolist] that it does not already enjoy.” However, Mallinckrodt’s reliance on *E&L*
 10 *Consult., Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2nd Cir. 2006), for this point is misplaced. Central
 11 to the court’s holding in *E&L* was the fact that the manufacturer in that case could have distributed
 12 the product itself and did not have to rely on the intermediary. *Id.* at 29. HCSC’s complaint does not
 13 suggest that Mallinckrodt had the ability to act as its own distributor; Mallinckrodt needed Express
 14 Scripts so that it could sell Acthar without interference from competing distributors who might
 15 impede Mallinckrodt’s ability to control Acthar’s price. And in *E&L*, unlike here, “nothing in the
 16 complaint suggest[ed] that th[e] agreement result[d] in . . . [an] effect on competition.” *Id.* at 29.

17 **B. Mallinckrodt Has Violated New Jersey’s RICO Act.**

18 Mallinckrodt does not for these purposes dispute that HCSC sufficiently alleges claims under
 19 New Jersey’s Racketeer Influenced and Corrupt Organizations Act (“RICO”), but instead attacks only
 20 certain categories of conduct. Mallinckrodt’s only challenge to the RICO claims is an argument that
 21 Mallinckrodt’s co-payment subsidy scheme with the Chronic Disease Fund does not qualify as
 22 commercial bribery. Separately, Mallinckrodt argues HCSC has not alleged kickbacks to Prescribing
 23 Doctors were unlawful. Both of these contentions lack merit.

24 “The gravamen of a RICO violation . . . is the involvement in the affairs of an enterprise
 25 through a pattern of racketeering activity.” *State v. Ball*, 141 N.J. 142, 155, 661 A.2d 251, 257 (1995).
 26 New Jersey defines “racketeering activity” broadly to include, among other things, “any conduct
 27 defined as ‘racketeering activity’ under Title 18, U.S.C. § 1961(1)(A), (B) and (D).” N.J. Stat. § 2C:41-
 28 1(a). In turn, 18 U.S.C. § 1961 defines “racketeering activity” to include acts indictable under 18

1 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct
 2 unlawful activity). The “enterprise” alleged by Plaintiffs includes the CDF charity and Mallinckrodt’s
 3 agents, such as “Prescribing Physicians” who issued Acthar prescriptions in exchange for bribes and
 4 kickbacks, and made false representations of compliance with federal laws. HCSC alleges that
 5 Mallinckrodt engaged in “a pattern of racketeering activity . . . including acts indictable under 18
 6 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct
 7 unlawful activity), and state bribery statutes[.]” These allegations sufficiently allege a violation of New
 8 Jersey RICO.

9 **1. HCSC’s Off-Label Promotion Allegations State a Cause of Action.**

10 HCSC states a claim under New Jersey RICO and its other causes of action that rely on
 11 Mallinckrodt’s off-label promotion because HCSC alleges that Mallinckrodt misrepresented to HCSC
 12 that it was complying with federal law, when in fact, Mallinckrodt had violated federal law by
 13 promoting Acthar for off-label indications. Mallinckrodt’s representations concerning its compliance
 14 with the law were false. HCSC alleges who made the misrepresentation (Mallinckrodt), to whom it
 15 was made (HCSC), what it was (that Mallinckrodt complied with federal law), when it was made
 16 (when Mallinckrodt made Acthar-related certifications to HCSC), and by what means it was made
 17 (through Mallinckrodt’s certifications to HCSC). Contrary to Mallinckrodt’s argument, the thrust of
 18 HCSC’s claims is **not** that the off-label promotions themselves were misrepresentations. Rather, it is
 19 the false statements of compliance with the law by Mallinckrodt (and Prescribing Doctors) that were
 20 false. Mallinckrodt’s arguments concerning lack of specificity are thus misguided. *See Humana*, 2020
 21 U.S. Dist. LEXIS 101378, at *48 (“Here, Plaintiff has alleged that the doctors prescribed Acthar
 22 because of the bribes and the availability of the co-pay assistance funds, and the false certifications
 23 from Defendant and the doctors directly caused Plaintiff to pay for Acthar in an amount and for a
 24 price higher than it otherwise would have absent the alleged illegal conduct.”).

25 To the extent more particulars are required about the inner-workings of Mallinckrodt’s off-
 26 label scheme, that information is within Mallinckrodt’s control and knowledge and need not be
 27 alleged for HCSC’s fraud-based claims to withstand demurrer. *See Comm. on Children’s Television, Inc. v.*
 28 *Gen. Foods Corp.*, 35 Cal. 3d 197, 216–17 (1983) (“Less specificity is required when it appears from the

1 nature of the allegations that the defendant must necessarily possess full information concerning the
 2 facts of the controversy”). Here, the allegations are “sufficient to enable the court to determine
 3 whether, on the facts pleaded, there is any foundation, *prima facie* at least, for the charge of fraud.” *Id.*
 4 at 217 (quotations omitted). No more is needed.

5 Mallinckrodt argues HCSC fails to allege causation for its fraud-based claims. Not so. HCSC
 6 alleges that it paid for Acthar prescriptions that it otherwise would not have because HCSC relied on
 7 Mallinckrodt’s misrepresentation that Mallinckrodt had complied with the law. No more is needed to
 8 sufficiently allege that Mallinckrodt’s misrepresentations caused HCSC injury.

9 Similarly, Mallinckrodt’s contention that doctors’ “independent medical judgment” breaks a
 10 causal chain is inconsistent with the allegations of the complaint and has been rejected by numerous
 11 courts. *See, e.g., In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39 (1st Cir. 2013) (rejecting
 12 argument that there were too many steps in causal chain between defendant’s off-label promotion and
 13 insurance company’s injuries); *In re Avandia Mktg.*, 804 F.3d 633, 645–46 (3d Cir. 2015) (rejecting
 14 argument “that the presence of intermediaries, doctors and patients, destroys proximate causation” of
 15 insurance company’s injuries flowing from defendant’s fraudulent pharmaceutical marketing); *United*
 16 *States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165, 2014 U.S. Dist. LEXIS 99815, at **30–32 (C.D.
 17 Cal. July 10, 2014) (“To suggest that [defendant’s] alleged expansive, multi-faceted efforts to create an
 18 off-label market for Thalomid and Revlimid did not cause physicians to prescribe Thalomid or
 19 Revlimid for non-reimbursable uses strains credulity.”). Exactly these same arguments were rejected in
 20 *Humana*. U.S. Dist. LEXIS 101378, at *47 (“here the doctors were allegedly bribed to prescribe Acthar
 21 and were participants in the RICO conspiracy. That causal link is far from attenuated.”).

22 Mallinckrodt’s reliance on *Sidney Hillman Health Center v. Abbott Labs.*, 873 F.3d 574, 577 (7th
 23 Cir. 2017) and *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) is misplaced
 24 because in those cases misrepresentations were made *to the doctors*, who were **innocent** conduits of the
 25 alleged falsehoods. There were no allegations that payors *themselves* relied on the false representations,
 26 and this was a “crucial[]” factor negating proximate cause. *UFCW*, 620 F.3d at 134; *see Sidney Hillman*,
 27 873 F.3d at 578 (distinguishing itself from case where “misrepresentations are made directly to
 28

1 Payors”). Here, by contrast, HCSC alleges that it was *itself* the victim of misrepresentations made
 2 directly by Mallinckrodt.

3 Mallinckrodt argues that because HCSC “pre-reviewed” certain claims, HCSC’s fraud claims
 4 are too attenuated. However, no causal chain was broken by HCSC’s claim review process, as the
 5 process was tainted by Mallinckrodt’s conduct and whatever HCSC may have reviewed did not
 6 disclose the crucial aspects of the scheme. *See Neurontin*, 712 F.3d at 38–41 (discussing how off-label
 7 promotion influences third party payor’s coverage determinations and rejecting argument that there
 8 are too many steps in causal chain between defendant’s off-label promotion and insurance company’s
 9 injuries). The argument also ignores the allegation that HCSC relied on physicians’ representations
 10 that the prescription was medically necessary, which representations, as discussed above, were
 11 influenced by the off-label promotion scheme.

12 2. HCSC’s Physician Kickback Allegations State a Cause of Action

13 Mallinckrodt argues that HCSC’s claims related to payments to physicians fail because (1)
 14 HCSC’s bribery allegations are conclusory, and (2) facts concerning causation are lacking.
 15 Mallinckrodt’s contentions contest the truth of the facts alleged, or ignore them altogether, and must
 16 be rejected.

17 HCSC alleges that payments Mallinckrodt made to physicians constitute undisclosed unlawful
 18 kickbacks supporting RICO and state law causes of action. Mallinckrodt does not dispute that HCSC
 19 sufficiently alleges that these payments constituted unlawful kickbacks in violation of the Medicare
 20 Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Contrary to Mallinckrodt’s assertion, HCSC
 21 sufficiently alleges that the unlawful physician kickbacks caused HCSC injury as Mallinckrodt and
 22 Prescribing Physicians made false statements about compliance with kickback and bribery laws.

23 Mallinckrodt’s arguments concerning bribery being conclusorily alleged are not well-taken,
 24 even if the Court agrees with Mallinckrodt that federal pleading standards apply. Contesting the facts
 25 supporting causation, Mallinckrodt posits that the payments are simply “industry standard”, and
 26 supporting studies such as the 2018 JAMA Network study showing with regression analysis that the
 27 percentage of doctors who receive financial assistance for prescribing Acthar is abnormally high get it
 28 wrong. *Id.* at 25-26. These arguments cannot be resolved by demurrer. *Comm. On Children’s Television*,

1 35 Cal. 3d at 213 (a demurrer does not “test the truth of the plaintiff’s allegations or the accuracy with
 2 which he describes the defendant’s conduct”). In any event, the JAMA study supports HCSC’s
 3 allegations that the payments from Mallinckrodt influenced doctor’s decision to prescribe Acthar, and
 4 the extent to which that is true will be determined in discovery.

5 Mallinckrodt’s causation arguments are misguided as they sweep aside the allegations that
 6 physicians did not, in fact, exercise “independent medical judgment.” *See Blue Cross of Cal. Inc. v. Insys*
 7 *Therapeutics Inc.*, 390 F. Supp. 3d 996, 1008 (D. Ariz. 2019) (“The thrust of [defendant’s] argument . . .
 8 is that, when prescribing Subsys, providers were exercising their independent medical judgment,
 9 which breaks the causal chain between [defendant’s] actions and [plaintiff’s] alleged injury. As pled,
 10 however, the complaint alleges that prescribers were not exercising independent medical judgment.
 11 That is, prescribers were prescribing Subsys in exchange for kickbacks.”); *United States ex rel.*
 12 *Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53 (D. Mass. 2011) (“Kickbacks are designed to
 13 influence providers’ independent medical judgment”); *State ex rel. Wilson v. Superior Court*, 227 Cal. App.
 14 4th 579, 606-07 (2014) (“Given a choice among two or more medically appropriate drugs, the reasons
 15 why a physician would prescribe one over another could include many possible factors, including not
 16 just the physician’s independent medical judgment as to the particular prescription, but also, for
 17 example, patient requests and preferences, direct advertising, relative costs of alternative treatments
 18 and drugs, dictates of institutional formularies, availability of particular drugs, insurance company
 19 preferences, and—of course—the unlawful conduct [unlawful physician kickbacks] in which
 20 [defendant] had engaged to induce such prescriptions.”).

21 Finally, Mallinckrodt argues that its settlement with regulators do not support an inference of
 22 wrongdoing generally, or alternatively that only misconduct from 2009 to 2013 is alleged. The DOJ
 23 settlement strongly supports HCSC’s claims that Mallinckrodt made illegal payments to prescribing
 24 physicians. *See, e.g., In re Nat’l Ass’n of Music Merchants, Musical Instruments & Equip. Antitrust Litig.*, 2011
 25 WL 3702453, at *2 (S.D. Cal. Aug. 22, 2011) (denying motion to strike references to FTC complaint
 26 and consent decree from pleading and holding that FTC consent decree enhanced plausibility of
 27 anticompetitive conduct allegations). Whatever weight the Court may give the settlements, however,
 28 HCSC provides ample supporting facts demonstrating a marketing scheme that persisted over many

1 years, including details about specific payments to certain physicians. HCSC's allegations that
 2 Mallinckrodt, at minimum, paid over \$27 million in improper payments "from 2013 to 2016" is
 3 dispositive of Mallinckrodt's contention that the wrongdoing is limited in time.

4 **C. HCSC States a Cause of Action for Tortious Interference With Contracts**

5 Mallinckrodt argues HCSC has not stated a claim for intentional interference because there
 6 has been no breach of contract by HCSC's customers. As the California Supreme Court has held,
 7 however, a claim can be stated by either "actual breach or disruption of the contractual relationship."
 8 *Pacific Gas & Electric Co. v. Bear Stearns & Co.*, 50 Cal.3d 1118, 1126 (1990) (citations omitted). Here,
 9 HCSC explicitly alleges disruption of contractual benefits because Mallinckrodt knowingly frustrated
 10 the operation of co-pay obligations that are designed to benefit all members by keeping costs low.

11 The Office of Inspector General ("OIG") advisory bulletin quoted by Mallinckrodt (MPA at
 12 24) is not dispositive of HCSC's tortious interference claim. That bulletin relates to *only* Medicare Part
 13 D beneficiaries, not other HCSC members. Because the court in *Humana* exclusively relied on the
 14 OIG guidance in dismissing the tortious interference claims, reliance on that case is misplaced. *See*
 15 MPA at 24; *Humana*, 2020 U.S. Dist. LEXIS 101378, at ** 49–50.¹

16 **D. Mallinckrodt's Insurance Fraud is Actionable**

17 In its request for judicial notice, Mallinckrodt argues that HCSC's claims under the laws of
 18 California and other states that purportedly do not provide a private right of action should be dismissed,
 19 and that claims for states that provide such a private right are time-barred, or otherwise deficient. These
 20 arguments are not properly raised, as demonstrated in HCSC's opposition to Mallinckrodt's RJN,
 21 because Mallinckrodt recitation of the law is inaccurate in some respects and legal claims should not be
 22 resolved through request for judicial notice. More specifically, Mallinckrodt is wrong that California,
 23 Kentucky, and Florida provide no private right of action in these circumstances.

24
 25
 26 ¹ Mallinckrodt's reliance on *Blue Cross of California Inc. v. Insys Therapeutics Inc.*, 390 F.Supp.3d 996, 1009
 27 (D. Az. 2019), is unavailing. That claim does not apply California law, and plaintiff did not allege that
 28 defendant "induced or caused a breach of this provisions of the members' contracts. . . . At most,
 [plaintiff] allege[d] that [defendant] interfered with a 'contractual incentive.'" *Id.*

Although many states do not have express rights of action for insurance fraud, such a right may be inferred here. A number of states have insurance fraud statutes in states that allow a government enforcer to pursue civil penalties for insurance fraud.² For these states that do not expressly provide a private cause of action, this Court recognizes an implied private cause of action in the statute. Many states have examined statutes similar to the insurance fraud statutes here and concluded that a private right of action exists even when it is not express in the statutory scheme. *See, e.g. Allstate Ins. Co. v. Parfrey*, 830 P.2d 905 (Colo. 1992) (concluding private right of action existed for violation of statute requiring that automobile liability insurers provide uninsured/underinsured motorist coverage to their insureds); *Napoletano v. CIGNA Healthcare of Connecticut, Inc.*, 680 A.2d 127, 145 (Conn. 1996) (determining private cause of action implied in Public Act governing managed care organizations), *overruled on other grounds by Batte-Holmgren v. Commissioner of Public Health*, 281 Conn. 277, 284-85 (2007). If the plaintiff is one for whose benefit the statute was enacted, there was expressly or implied legislative intent to create such a remedy, and it is consistent with the underlying purpose of the statute to imply such a remedy for the plaintiff, then a private remedy is implicit in the statute. *See Cort v. Ash*, 422 U.S. 66 (1975).

An implied private right of action should likewise be recognized under the statutes at issue here. *See* fn. 3. The insurance fraud statutes are designed to benefit those paying increased costs due to insurance fraud, and so payors like HCSC would fall within this specific group of plaintiffs. The statutes here have not express prohibition on private litigants pursuing actions, which they would have done if they wanted to forbid private actions. Finally, the purposes of the insurance fraud statutes are to deter this type of conduct and recouping some of the overcharges that result from this fraud. Allowing a private cause of action under the insurance fraud statute would accomplish both of these goals.

E. HCSC's Claims Are Timely.

Mallinckrodt seeks dismissal based on the statute of limitations for HCSC's claims flowing from the CDF Co-Pay Scheme and its acquisition of Synacthen. Mallinckrodt relies on facts from

² These statutes are: Ariz. Rev. Stat. §§ 20-463, et seq.; Ark. Code §§ 23-66-501, et seq.; Colo. Rev. Stat. § 10-1-128, et seq.; Iowa Code Ann. §§ 505.1, et seq.; Me. Rev. Stat. Ann. tit. 24-A, §§ 2186; Md. Code Ins. §§ 27-401, et seq.; Mo. Rev. Stat. §§ 375.99, et seq.; Mont. Code §§ 33-1-1202, et seq.; Neb. Rev. Stat. §§ 44-6604, et seq.; N.D. Cent. Code §§ 26.1-01, et seq.; N.M. Stat. §§ 59A-16C-1, et seq.; Okla. Stat. tit. 36, §§ 101, et seq.; and S.C. Code §§ 38-55-570, et seq.

1 purportedly judicially noticeable documents, which cannot be used on demurrer to resolve factual
 2 disputes about issues such as notice for purposes of the statute of limitations. *StorMedia, Inc. v. Superior*
 3 *Court*, 20 Cal.4th 449, 457, fn. 9 (1999) (“When judicial notice is taken of a document, however, the
 4 truthfulness and proper interpretation of the document are disputable.”).

5 Although the wrongdoing alleged by HCSC stretches back over ten years, HCSC alleges it did
 6 not become aware of the scheme now alleged until federal investigations, including the FTC’s
 7 investigation of antitrust claims and the DOJ’s claims concerning fraudulent sales practices, were
 8 disclosed. None of the facts or documents Mallinckrodt seeks to judicially notice can defeat these
 9 allegations. Moreover, the doctrines of fraudulent concealment and ongoing violation make all of
 10 HCSC’s claims timely.

11 As an initial matter, HCSC is a putative class member in two separate class actions filed in April
 12 and October of 2017. *See City of Rockford v. Mallinckrodt ARD, Inc.*, No. 3:17-cv-50107 (N.D. Ill.) and
 13 *MSP Recovery Claims, Series LLC et al v. Mallinckrodt ARD Inc., et al.*, No. 2:17-cv-07928 (C.D. Cal.). With
 14 respect to its antitrust claims, HSCS is entitled to tolling as of the date those complaints were filed,
 15 because in those cases HCSC is a putative member of the classes and its antitrust claims share a common
 16 factual and legal basis with the class claims. *Am. Pipe & Constr. Co. v. Utah*, 414 U.S. 538 (1974).

17 **1. Mallinckrodt Fails to Show Any Claim Is Time Barred.**

18 All of Mallinckrodt’s arguments fail because they rely on facts from judicially-noticed
 19 documents, which cannot be credited over HCSC’s allegations that it discovered the wrongdoing when
 20 the results of government investigations became public. *Richtek USA, Inc. v. uPI Semiconductor Corp.*, 242
 21 Cal. App. 4th 651, 660 (2015) (it is “improper” to consider on demurrer facts from a judicially noticed
 22 document that are “contrary to the allegations” in the complaint). For this reason alone, the demurrer
 23 must be overruled in its entirety.

24 Mallinckrodt argues that HCSC was on constructive notice of, and should have discovered, its
 25 claims “at least six years ago” because “the precise manner in which HCSC alleges the CDF funds
 26 violated the AKS has long been in the public record.” The court in *Humana* rejected Mallinckrodt’s
 27 precise argument. *Humana*, 2020 U.S. Dist. LEXIS 101378, at **33 –37. Here, as in *Humana*, it “is not
 28 alleged . . . that Plaintiff was in any way notified whether co-pays were subsidized by assistance funds.

1 In fact, Plaintiff's allegations about its members indicate otherwise." *Id.* at *34. "The mere receipt or
 2 payment of claims, when there is no reason to think that Plaintiff knew those claims were fraudulent
 3 or excessive when it paid them, does not establish constructive knowledge of plaintiff's injury."
 4 *Humana*, 2020 U.S. Dist. LEXIS 101378, at *35 (quotations and brackets omitted). And similar to
 5 *Humana*, there is nothing in HCSC's complaint "that indicates the allegedly illegal aspects of
 6 Defendant's co-pay assistance program were widely publicized, or that the information to be gleaned
 7 from the purported publicity could be imputed to Plaintiff." *Id.*, citing *Living Designs, Inc. v. E.I. Dupont*
 8 *de Nemours & Co.*, 431 F.3d 353, 365 (9th Cir. 2005) ("[T]he district court erred in determining that, as
 9 a matter of law, the attention received by [a sanction order against defendants] could be imputed to
 10 the Plaintiffs"). Further, HCSC alleges that the donation agreements fraudulently misrepresented that
 11 the funds were not limited to patients using Acthar. Therefore, had HCSC "inquired into the funds, it
 12 would not have discovered that the funds were illegal." *See Humana*, 2020 U.S. Dist. LEXIS 101378, at
 13 *36.

14 Mallinckrodt contends that HCSC was put on constructive suspicion of its injuries by mere
 15 publication of two news articles and a guidance bulletin, the latter of which made no reference to
 16 Acthar. However, the concept of "constructive suspicion" was rejected in *Nelson v. Indevus Pharm., Inc.*,
 17 142 Cal.App.4th 1202, 1204–06 (2006); *id.* at 1206 ("The statute of limitations does not begin to run
 18 when some members of the public have a suspicion of wrongdoing, but only once the plaintiff has a
 19 suspicion of wrongdoing.") (quotations and brackets omitted); *see also Unruh-Haxton v. Regents of Univ.*
 20 *of Cal.*, 162 Cal.App.4th 343, 364 (2008) (rejecting idea "that public awareness of a problem through
 21 media coverage alone creates constructive suspicion for purposes of discovery."); *Gryczman v. 4550*
 22 *Pico Partners, Ltd*, 107 Cal.App.4th 1, 6 (2003) ("we cannot say as a matter of law plaintiff had a duty to
 23 continually monitor public recordings"). Two articles, which themselves cast doubt on whether CDF
 24 was controlled by Mallinckrodt, cannot constitute notice under these circumstances. Defs' RJN, Ex. C
 25 at 21, 23 (CDF received funds from Novartis, Genentech, Roche; "collaboration" was a "savvy
 26 move[]" that increased stock price; and outside counsel represented "There is no steering that takes
 27 place whatsoever."); Ex. D at 27 ("Questcor and the charity have said they are victims of a campaign
 28 by short-sellers"). Moreover, none of the materials cited by Mallinckrodt say anything of the off-label

1 marketing, or other aspects of the scheme to inflate demand.

2 **2. Fraudulent Concealment Tolls HCSC's Claims.**

3 HCSC's claims are timely because Mallinckrodt fraudulently concealed its wrongdoing. "[T]he
4 fraudulent concealment by the defendant of a cause of action tolls the relevant statute of limitations,
5 which does not begin to run until the aggrieved party discovers the existence of the cause of action."
6 *Cnty. Cause v. Boatwright*, 124 Cal. App. 3d 888, 899 (1981). HCSC alleges it could not have discovered
7 Mallinckrodt's wrongdoing earlier because it repeatedly and falsely represented to HCSC it was
8 complying with federal law. These allegations are sufficient to toll the statute of limitations on HCSC's
9 claims.

10 **2. The "Continuing Violation" Doctrine Prevents Dismissal Because**
11 **Mallinckrodt Continues to Overcharge for Acthar.**

12 HCSC's antitrust claims premised on the purchase of Synacthen continue to accrue because
13 HCSC alleges that it is suffering "continuing harm" in that it continues to pay for Acthar
14 prescriptions. "Antitrust law provides that, in the case of a 'continuing violation,' . . . each overt act
15 that is part of the violation and that injures the plaintiff, *e.g.*, each sale to the plaintiff, starts the
16 statutory period running again, regardless of the plaintiff's knowledge of the alleged illegality at much
17 earlier times." *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997) (quotations omitted); *In re Pre-Filled*
18 *Propane Tank Antitrust Litig.*, 860 F.3d 1059, 1065-66 (8th Cir. 2017) ("Every other circuit to consider
19 this issue applies *Klehr*, holding that each sale in a price-fixing conspiracy is an overt act that restarts
20 the statute of limitations"). The idea that "continued overcharges constitute a continuing violation"
21 applies with equal force in drug monopoly cases. *In re Glumetza Antitrust Litig.*, 2020 U.S. Dist. LEXIS
22 39649, at **24–27 (N.D. Cal. Mar. 5, 2020) (applying doctrine in action challenging reverse payment
23 settlement and collecting cases); *see also In re Buspirone Patent & Antitrust Litig.*, 185 F.Supp.2d 363, 378
24 (S.D.N.Y. 2002) ("[I]f a party commits an initial unlawful act that allows it to maintain market control
25 and overcharge purchaser for a period longer than four years, purchasers maintain a right of action for
26 any overcharges paid within four years prior to their filings.").

27 Mallinckrodt contends that the continuing violation doctrine does not apply "because once an
28 acquisition is completed 'no overt acts can be undertaken to further that plan.'" However,

1 Mallinckrodt's reliance on *Midwestern Mach. Co., Inc. v. Northwest, Airlines, Inc.*, 392 F.3d 265, 271 (8th
 2 Cir. 2004), is misplaced because the case concerned a merger in violation of the Clayton Act, which
 3 has no continuing violation doctrine. *Id.* at 271 ("A continuing violation theory based on overt acts
 4 that further the objectives of an antitrust conspiracy in violation of § 1 of the Sherman Act or that are
 5 designed to promote a monopoly in violation of § 2 of that act cannot apply to mergers under § 7 of
 6 the Clayton Act.")³

7 Here, HCSC alleges that Mallinckrodt's acquisition of Synacthen and its subsequent shelving
 8 was in furtherance of its continuing monopoly in the ACTH market that included lying about the
 9 intentions of the transaction itself. *Cf. In re Evanston Northwestern Healthcare*, 2008 U.S. Dist. LEXIS
 10 42437, at *14 (N.D. Ill. May 29, 2008) ("Although it may be likely that plaintiffs knew or should have
 11 known of their potential injury at the time the merger was consummated, neither the legal precedents
 12 cited by ENH nor the allegations pleaded in plaintiffs' complaint definitively require such a
 13 conclusion); *see also Nexium*, 968 F.Supp.2d at 399–400 (rejecting similar argument based on
 14 *Midwestern*, explaining that "[a]lthough the business of a monopolist's rival may be injured at the time
 15 the anticompetitive conduct occurs, a purchaser, by contrast, is not harmed until the monopolist
 16 actually exercises its illicit power to extract an excessive price.")⁴

17 IV. Conclusion

18 For the foregoing reasons, Mallinckrodt's demurrer is OVERRULED in its entirety.

19
 20 Dated: _____, 2020

IT IS SO ORDERED.

21
 22
 23 _____
 24 ³ Mallinckrodt's reliance on *Midwestern* to defeat fraudulent concealment is also misplaced. *Midwestern*
 did not concern a claim of fraudulent concealment, nor did it concern a "catch and kill" scheme
 contrary to false claims to develop the drug.

25 ⁴ *Z Techs Corp. v. Lubrizol Corp.*, 753 F.3d 594 (6th Cir. 2014), does not help Mallinckrodt either. There,
 26 the court recognized that the continuing violations doctrine applies to claims, where, as here, "a party
 27 unilaterally monopolized a market or undertook action, in addition to price increases, to monopolize a
 28 market." *Id.* at 598; *id.* at 599 ("this court has applied the continuing violations doctrine . . . to
 unilateral monopolization claims when a party already possesses a monopoly and takes action to
 preserve the monopoly[.]")

Hon. Stephen Krause
Judge of the Superior Court

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EXHIBIT 44

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**[PROPOSED] ORDER RE
DEFENDANTS' REQUEST FOR
JUDICIAL NOTICE IN SUPPORT OF
THE DEFENDANT MALLINCKRODT
ENTITIES' DEMURRER AND MOTION
TO STRIKE**

Judge: Hon. Stephen Kaus

Location: Dept. 19

Hearing: August 5, 2020; 3:00 p.m.

Complaint Filed: February 27, 2020

Trial Date: Not Set

1 **I. INTRODUCTION**

2 Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (together, “Mallinckrodt”),
3 requested that the Court take judicial notice of certain documents in support of their demurrer to, and
4 motion to strike certain allegations from, the complaint of plaintiff Health Care Services Corporation
5 (“HCSC”), filed on February 27, 2020. Being fully advised in the matter and good cause appearing,
6 the Court rules as follows on Mallinckrodt’s Request for Judicial Notice (“RJN”).

7 **II. LEGAL STANDRD FOR JUDICIAL NOTICE**

8 Matters are “subject to judicial notice only if the matter is reasonably beyond dispute.” *Tenet*
9 *Healthsystem Desert, Inc. v. Blue Cross of California*, 245 Cal. App. 4th 821, 835 (2016). A demurrer may
10 not be turned into a contested evidentiary hearing through the guise of having the court take judicial
11 notice of documents whose truthfulness or proper interpretation are disputable. *Fremont Indem. Co. v.*
12 *Fremont Gen. Corp.*, 148 Cal. App. 4th 97, 114 (2007). While the existence of a document may be
13 judicially noticeable, the truth of statements contained in the document and their proper
14 interpretation are not subject to judicial notice. *Tenet Healthsystem Desert, Inc.*, 245 Cal. App. 4th 821 at
15 836; *see also Aquila, Inc.*, 148 Cal. App. 4th at 569 (“[T]he taking of judicial notice of the official acts of
16 a governmental entity does not in and of itself require acceptance of the truth of factual matters which
17 might be deduced therefrom”).

19 **III. ANALYSIS**

20 A. Mallinckrodt Improperly Seeks to Judicially Notice Disputed Facts.

21 California courts draw a distinction between judicial notice of the existence of a document,
22 and judicial notice of the truth of the contents of a document. “Strictly speaking, a court takes judicial
23 notice of facts, not documents.” *Scott v. JPMorgan Chase Bank, N.A.*, 214 Cal. App. 4th 743, 755 (2013).
24 Thus while courts are permitted to take judicial notice of the “existence” of documents in ruling on a
25 demurrer, as the California Supreme Court explained in *StorMedia Inc. v. Superior Court*, 20 Cal. 4th 449,
26 457 n.9 (1999), “[w]hen judicial notice is taken of a document... the truthfulness and proper
27 interpretation of the document are disputable.” While “a court may take judicial notice of a recorded
28

1 deed, or similar document,” the Court may not “take judicial notice of factual matters stated therein.”
 2 *Poseidon Dev., Inc. v. Woodland Lane Estates, LLC*, 152 Cal. App. 4th 1106, 1117 (2007); *see also Ragland v.*
 3 *U.S. Bank Nat’l Ass’n*, 209 Cal. App. 4th 182, 193 (2012) (“Although the audit report is a government
 4 document, we may not judicially notice the truth of its contents.”).

5 Mallinckrodt disregards these well-established principles in seeking to cherry-pick statements
 6 from documents outside the pleadings in support of its demurrer and motion to strike.

7 **1. Mallinckrodt Improperly Relies on Facts in Exhibits A through D to**
 8 **Make Arguments Regarding the Statute of Limitations.**

9 Mallinckrodt improperly relies on the truth of matters contained in Exhibits A through D to
 10 argue that HCSC was on “constructive notice” of the facts and how they relate to HCSC’s claims. It is
 11 well established that a court may not use media sources to create “constructive suspicion” of the
 12 existence of facts to trigger the statute of limitations. *Unruh-Haxton v. Regents of Univ. of Cal.*, 162 Cal.
 13 App. 4th 343, 365, 76 Cal. Rptr. 3d 146, 164 (2008) (“the court interpreted the widespread media
 14 coverage to conclusively refute the patients’ allegations they either (1) did not see or read the media
 15 coverage, or (2) saw the publicity, but failed to discover any wrongdoing. [J]udicial notice was
 16 improperly taken in both instances.”).

17 Mallinckrodt’s request with respect to two news articles from *Barrons* and *The New York Times*
 18 is an improper attempt to introduce evidence of when HCSC was on notice of certain allegations. See
 19 RJN Ex. C and D; *see also Voris v. Lampert*, 7 Cal. 5th 1141, 1147, (2019) (declining to take judicial
 20 notice of newspaper articles that were “not proper authorities to establish the truth of the matters
 21 asserted therein.”); *People ex rel. Lockyer v. Shamrock Foods Co.*, 24 Cal. 4th 415, (2000) (refusing to take
 22 judicial notice of articles not relevant to state statutory issue).

23 Similarly, Mallinckrodt relies on guidance from the Department of Health and Human
 24 Services Office of Inspector General (“OIG”) concerning co-payments for Medicare Part D enrollees
 25 in 2005 (Ex. A) and May 2014 (Ex. B) arguing they provide “constructive notice” to HCSC. This is
 26 another improper use of judicial notice: neither document can be used to establish a date of discovery
 27 that is different from that which is alleged by HCSC. HCSC alleges it discovered the wrongdoing after
 28 federal investigations were made public. Those allegations are entitled to the presumption of truth.

1 *Richtek USA, Inc. v. uPI Semiconductor Corp.*, 242 Cal. App. 4th 651, 660 (2015) (it is “improper” to
 2 consider on demurrer facts from a judicially noticed document that are “contrary to the allegations” in
 3 the complaint).

4 Exhibits A and B cannot provide any type of constructive notice because they disclose no
 5 wrongdoing. Neither Exhibit A nor B mentions Acthar at all, and in no sense would they put a
 6 reasonable person on notice of any wrongdoing. Nor does Exhibit A establish that HCSC reviewed
 7 this document in 2005—prior to when the wrongdoing alleged here began—or at any other time.
 8 With respect to Exhibit B, it too has no indicia of HCSC having reviewed it.

9 Mallinckrodt’s request for judicial notice of the contents of Exhibits A through D is
 10 DENIED to the extent Mallinckrodt asks the Court to assume the truth of the content.

11 2. **Mallinckrodt Makes Improper Use of Exhibits I & H to Dispute the**
 12 **Truth of Other Facts HCSC Alleges.**

13 Mallinckrodt seeks judicial notice of facts contained within a DOJ press release (Ex. H), which
 14 Mallinckrodt seeks to use to establish the fact that the DOJ allegations “were limited to the conduct
 15 of ‘twelve Questcor sales representatives’ ‘from 2009 and 2013.’” RJN at 4. Mallinckrodt uses Ex. H to
 16 invent a fact—that its sales representative misconduct ended in 2013—that is not found anywhere in
 17 press release. Mallinckrodt improperly attempts to use this document to establish the truth of its
 18 contention that there was no actionable misconduct concerning sales representatives from 2014 to the
 19 present. This is contradicted by HCSC’s specific allegations that identify similar kickbacks and
 20 improper payments to doctors into 2016. The DOJ’s Complaint in intervention contradicts the fact
 21 Mallinckrodt improperly seeks to notice. *See* Pl.’s’ Request for Judicial Notice, Ex. 2; Complaint,
 22 *United States of America ex rel. Strunck*, No. 12-cv-0175 (E.D. Pa. June 4, 2019) at Exhibits 1 to 4
 23 (alleging and documenting false claims through 2014).

24 Mallinckrodt similarly makes improper use of judicial notice in seeking notice Exhibit I, an
 25 article published in the JAMA Open Network in 2018 that Mallinckrodt contends makes certain of
 26 HCSC’s allegations “implausible.” The JAMA study supports HCSC’s allegations that the payments
 27 from Mallinckrodt influenced doctor’s decision to prescribe Acthar by comparing the correlation
 28 between payments to prescribing doctors and Acthar prescriptions written, finding a statistically

1 significant correlation. As a threshold matter, scientific articles that have bearing on disputed issues
 2 cannot be judicially noticed. *People v. Ireland*, 33 Cal. App. 4th 680, 685 (1995) (“As to the scientific
 3 literature, we take judicial notice only to the existence of the writings; the truth of the scientific claims
 4 written about cannot be judicially noticed, but must be proved, since some of those claims are
 5 currently the subject of controversy.”)

6 Mallinckrodt contends that because the JAMA article says its “conceivable” that something
 7 else other than bribes was causing the high incidence of prescription, HCSC’s allegation is
 8 implausible. *See* RJN Ex. I at 84 (“[T]he temporal sequence between payments and prescriptions
 9 cannot be definitely established.”). Once again, Mallinckrodt attempts to extrapolate from documents
 10 the truth of a fact that is found nowhere in the document itself. The JAMA article expressly does **not**
 11 say that other behavior caused higher incidence of Acthar, it simply states that it studied the
 12 remarkable correlation and not the underlying causes. In any event, HCSC’s other allegations strongly
 13 support causation.

14 Mallinckrodt’s request for judicial notice of Exhibits H and I is DENIED.

15 B. Mallinckrodt’s Request to Judicially Notice Other State Laws and Cases Interpreting
 16 the Same Exceeds the Allowed Scope of Judicial Notice.

17 Mallinckrodt seeks judicial notice of five tables purporting to be compilations of out of state
 18 authorities relating to HCSC’s state law claims. *See* RJN Exhibits K-O. These tables, however, are not
 19 complete quotations of the relevant statutes and only include cherry-picked sections, along with
 20 citations to caselaw that Mallinckrodt believes is favorable to its position. General suppositions about
 21 the legal developments cannot be judicially noticed. *See Barker v. Garza*, 218 Cal. App. 4th 1449, 1452,
 22 n 1 (2013) (declining to take judicial notice of article about model Drug Dealer Liability Act and
 23 portions of law review article interpreting same because information contained in those sources was
 24 reasonably subject to dispute and plaintiff did not provide sufficient information to determine if
 25 judicial notice is proper). HCSC objects to all of Exhibits K through O because they resemble self-
 26 published law review articles, which are not an enumerated part of the Evidence Code. *See Cty. of*
 27 *Orange v. Smith*, 132 Cal. App. 4th 1434, 1450, 34 Cal. Rptr. 3d 383, 395 (2005) (“Evidence Code
 28 section 452 enumerates the matters of which a court may take judicial notice. Law review articles are

1 not listed in either of those statutory provisions.”).

2 Mallinckrodt’s presentation of the laws in the table are argumentative, and not a complete and
3 accurate picture of the relevant statutory language.

4 **Exhibit K:** HCSC objects to the legal conclusions drawn in the Exhibit K, which purport to
5 recite statutory enforcement mechanisms, as this is beyond the scope of appropriate judicial notice.
6 Mallinckrodt’s request is filled with improper contentions and arguments.¹ Mallinckrodt’s contentions
7 concerning application of states’ laws is beyond the “decisional ... law” of a state that may be judicial
8 noticed under Evidence Code Section 452(a).

9 Mallinckrodt’s recitation of these laws is also inaccurate. Mallinckrodt argues that Kentucky’s
10 law requires a conviction for there to be a private right of action for insurance fraud claim (Ex. K at
11 127), but Kentucky repealed this provision in 2018. *See* Declaration of Matthew S. Weiler, Ex. 4 (2018
12 Kentucky Laws Ch. 178 (HB 323) (removing requirement of a “criminal adjudication of guilt” for a
13 private party to state a claim for damages)).

14 California permits insurers to bring *qui tam* actions for private insurance fraud. *See People ex rel.*
15 *Allstate Ins. Co. v. Sub*, 37 Cal.App.5th 253, 255 (2019); Cal. Ins. Code § 1871.7; Cal. Penal Code § 550;
16 Moreover, an insurance fraud claim does not require an affirmative misstatement of fact, only one
17 that is “characterized by deceit.” *People ex rel. Allstate Ins. Co*, 37 Cal.App.5th 253 at 260. California’s
18 Unfair Competition Law (“UCL”) also allows for a private action violation predicated on violation of
19 the Insurance Code, and an implied private right of action where an express right does not exist. *See*
20 *Hangerter v. Paul Revere Life Ins. Co.*, 236 F. Supp. 2d 1069, 1107 (N.D. Cal. 2002) (allowing UCL claim
21 based on violation of California’s insurance code); *Stevens v. Superior Court*, 75 Cal. App. 4th 594, 606,
22 (1999) (allowing violation of insurance code licensing requirements as basis for UCL claim because
23 UCL “allows nearly any law or regulation to serve as its basis unless the predicate statute explicitly
24 bars a private right of action.”).

25
26
27 ¹ RJN Ex. K at 127, 129, 130 (“HCSC fails to allege actual injury from the alleged violation.”); *id.* at
28 129 (arguing HCSC’s claims under New Jersey Insurance Fraud Prevention lack specificity); *id.* at 130
(arguing HCSC’s claims fail Pennsylvania pleading standard); *id.* (arguing claims under Tennessee
Insurance Fraud Act are time-barred).

Contrary to Mallinckrodt's contention (Ex. K at 126), Florida permits a private insurer to pursue a civil insurance fraud claim. *Molina v. Provident Life and Accident Ins. Co.*, 18-24413-CV, 2019 WL 3429889, at *3 (S.D. Fla. May 31, 2019), *report and recommendation adopted*, 18-24413-CIV, 2019 WL 7937935 (S.D. Fla. June 27, 2019). While Florida's statutes have incorporated criminal liability into the statute, the requirement of a criminal conviction before pursuing a civil penalty has been thrown into question. *See Nationwide Mut. Co. v. Ft. Myers Total Rehab Ctr., Inc.*, 657 F. Supp. 2d 1279, 1287 (M.D. Fla. 2009) ("Nothing in this statute provides that a cause of action exists only if there is a conviction, or that other causes of action are pre-empted."). Thus, the Court should allow HCSC's insurance fraud claim under Florida law to proceed.

Similarly, Mallinckrodt argues that "HCSC fails to allege that it complied with the procedures provided in the New Jersey Insurance Fraud Prevention Act." Ex. K at 129. But the New Jersey IPFA only requires that "pleadings" and "briefs" be sent to the New Jersey Attorney General "at the time of filing." N.J. Stat. § 17:33A-7(c). This procedural provision is not an element of a New Jersey insurance fraud claim and is no basis for dismissal of HCSC's claim. *Cf. In re Generic Pharm. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 835 (E.D. Pa. 2019) (declining to dismiss claims under statutes with more stringent pre-suit notice requirements because "they do not alter the substantive elements of Plaintiffs' claims and are not a pleading requirement for the Complaints").

Exhibit L: HCSC objects to the entire exhibit, purportedly showing what states adopt the rule of reason for certain vertical restraints, because it is irrelevant. Mallinckrodt supplies the laws to support their contention that the exclusive distribution allegations should be viewed in isolation and examined under the rule of reason. MPA at 18. Mallinckrodt's characterization of states purportedly "Adopting Rule of Reason for Nonprice Vertical Restraints" should be rejected as it mischaracterizes HCSC's allegations, which allege a price-fixing and monopolization scheme. As HCSC does not simply allege vertical restraints, the Exhibit L supplies the wrong legal paradigm for HCSC's claims.

The Court need not, at this juncture, determine whether HCSC's claims are subject to the per se rule of illegality or the rule of reason: "While courts generally assess exclusive dealing arrangements under the rule of reason analysis, it is less clear that the rule of reason analysis applies here where plaintiffs have alleged that the conspiracy included both the exclusive dealing arrangement and the

1 Synacthen Acquisition, which plaintiff argues deserves a ‘per se’ analysis. However, the court agrees
 2 with plaintiffs that the court need not make this determination at this time.” *City of Rockford v.*
 3 *Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 754 (N.D. Ill. 2019); *In re: EpiPen (Epinephrine Injection,*
 4 *USP) Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256, 2018 WL 3973153, at *19 n.8 (D.
 5 Kan. 2018) (“In ruling [on a motion to dismiss], the court just needs to determine whether the class
 6 plaintiffs have alleged a plausible conspiracy under the antitrust laws.”); *CSR Ltd. v. Fed. Ins. Co.*, 40 F.
 7 Supp. 2d 559, 564 (D.N.J. 1998) (“At this early [motion to dismiss] stage of the proceeding, the court
 8 does not find it necessary to determine which mode of analysis [per se or rule of reason] it will
 9 ultimately employ in evaluating the defendants’ activities.”); *In re High-Tech Employees’ Antitrust Litig.*,
 10 856 F. Supp. 2d 1103, 1122 (N.D. Cal. 2012) (“Defendants’ argument relies on the false assumption
 11 that the Court should apply a rule of reason analysis, but as the parties agree ... the Court need not
 12 decide now whether per se or rule of reason analysis applies. Indeed, that decision is more appropriate
 13 on a motion for summary judgment.”).

14 **Exhibits M & O:** HCSC objects to Mallinckrodt’s chart reciting state law unfair practices
 15 statutes of limitations and “other defenses” (Exhibit M), and statute of limitations for antitrust claims
 16 (Exhibit O), because none of the issues Mallinckrodt raises concerning the application of the statute
 17 of limitations can be resolved on the record before the Court on demurrer.

18 With respect to Exhibit M, as with Exhibit K, Mallinckrodt makes a number of legal
 19 arguments against the application of certain states’ laws that is inappropriate for a request for judicial
 20 notice. See RJN Ex. M at 141 (Maine law claim barred based on contention “allegedly unlawful
 21 conduct discontinued over five years before HCSC filed its Complaint”); *id.* (Michigan law claim
 22 barred based on exemption defense); *id.* (Minnesota law claim barred as only injunctive relief and
 23 attorneys’ fees may be recovered); *id.* at 142 (raising as a defense privity under North Dakota law); *id.*
 24 (arguing HCSC’s purchases were outside scope of consumer statute); *id.* at 143 (same with respect to
 25 Vermont law). The Court should deny judicial notice of these arguments and disregard them in
 26 resolving Mallinckrodt’s demurrer and motion to strike.

27 With respect to Exhibit O, judicial notice of the statute of limitations period needs to be
 28 considered in connection with rules concerning accrual, as well as HCSC’s allegations of continuing

1 violation and fraudulent concealment. It would be a waste of judicial resources to judicially notice
2 these materials in a vacuum, when none of these laws require dismissal here.

3 **Exhibit N:** Exhibit N, purporting to summarize various state laws concerning antitrust injury,
4 is irrelevant. The Court need not judicially notice dozens of state laws when resolving the demurrer
5 because under *any* state's law HCSC pleads the common sense elements of antitrust injury, namely
6 that "but for Mallinckrodt's monopolistic conduct, including its acquisition of Synacthen, HCSC
7 would have benefitted from increased competition in the market for ACTH drugs and would have
8 either paid lower prices for Acthar or steered its members to lower priced Synacthen."

9 Mallinckrodt's request for judicial notice of Exhibits K through O is DENIED.

10 C. Judicial Notice of Exhibit E is Denied.

11 Although included in its RJN, Mallinckrodt does not cite to Exhibit E anywhere in its
12 demurrer or supporting memorandum of law, and so the Court will not take judicial notice because
13 the document is not relevant. *Aquila, Inc. v. Superior Court*, 148 Cal. App. 4th 556, 569 (2007) (only
14 "relevant material may be noticed."). Mallinckrodt's request for judicial notice of Exhibit E is
15 DENIED.
16

17 D. Judicial Notice of the Existence of Exhibits A, B, F, G, and J Is Granted.

18 HCSC not dispute that the Court should take judicial notice of some of the documents in
19 Mallinckrodt's RJN. HCSC agrees that the Court should take judicial notice of Exhibit J, *Humana Inc.*
20 *v. Mallinckrodt ARD LLC*, No. CV 19-06926 (C.D. Cal. Mar. 9, 2020). However, no factual findings
21 from the *Humana* case are applicable here, and the *Humana* decision is not binding precedent.
22

23 HCSC does not oppose the Court taking judicial notice of the Center for Drug Evaluation and
24 Research ("CDER") letter and labeling documents as executive department records. *See* Cal. Evid.
25 Code § 452(c); RJN Ex. F and G. The Court will take notice of the entirety of these documents and
26 not only those portions excerpted by Mallinckrodt in its demurrer.

27 Finally, the 2004 and 2014 OIG advisory opinions are both documents appearing in the
28 Federal Register and are judicially noticed. *See* Cal. Evid. Code § 451; RJN Exs. A and B. However, as

1 explained above, these documents may not be used to show that HCSC was on constructive notice of
2 claims against it.

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4 Dated: _____, 2020

IT IS SO ORDERED.

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Hon. Stephen Krause
Judge of the Superior Court

Submitted by:

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KONECKY LLP**

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[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**DECLARATION OF MATTHEW S.
WEILER**

Judge: Hon. Stephen Kaus
Location: Dept. 19
Hearing: August 5, 2020; 3:00 p.m.

Complaint Filed: February 27, 2020

Trial Date: Not Set

1 I, Matthew S. Weiler, declare:

2 1. I make this declaration on my own personal knowledge and if called to testify on these
3 matters, I could do so competently.

4 2. I am an attorney with Schneider Wallace Cottrell Konecky LLP, counsel of record for
5 Plaintiff Health Care Service Corporation (“HCSC”). I am duly licensed to practice law in California.
6 I make this declaration in support of HCSC’s (1) Request for Judicial Notice in Support of
7 Opposition to Defendants Mallinckrodt ARD LLC and Mallinckrodt plc’s (“Mallinckrodt’s”)
8 Demurrer and Motion to Strike, and (2) Opposition to Mallinckrodt’s Request for Judicial Notice in
9 Support of Mallinckrodt’s Demurrer and Motion to Strike, concurrently filed herewith.
10

11 3. Attached hereto as Exhibit 1 is a true and correct copy of an order issued by the
12 United States District Court for the Eastern District of Pennsylvania in *United States of America ex rel.*
13 *Strunck*, Case No. 12-cv-0175 (the “*Strunck*” matter), bearing the date of March 8, 2019.

14 4. Attached hereto as Exhibit 2 is a true and correct copy of a Complaint in intervention
15 filed by the U.S. Department of Justice in *the Strunck* matter bearing the date of June 4, 2019.
16

17 5. Attached here as Exhibit 3 is a true and correct copy of a press release issued by the
18 U.S. Department of Justice entitled “United States Intervenes in False Claims Act Lawsuit Against
19 Drug Maker Mallinckrodt Alleging Illegal Kickbacks,” bearing a date of June 5, 2019. This exhibit was
20 created using the following Internet weblink: <https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-drug-maker-mallinckrodt-alleging>.
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HCSC v. Mallinkrodt ARD LLC, Case No. RG20056354

Exhibit 1 to Declaration of Matthew S. Weiler

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FILED

UNITED STATES OF AMERICA et al., ex rel. :
CHARLES STRUNCK, :

Plaintiffs, :

v. :

QUESTCOR PHARMACEUTICALS, INC., :

Defendant. :

MAR - 8 2019

KATE BARKMAN, Clerk
3y _____ Dep. Clerk

Civil Action No. 12-CV-0175

FILED UNDER SEAL

ORDER

The United States having intervened in this action, pursuant to the False Claims Act, 31 U.S.C. § 3730(b)(4), the Court rules as follows:

IT IS ORDERED that,

1. the relator's Fourth Amended Complaint, the Government's Notice of Election to Intervene, and this Order be unsealed;
2. the United States shall file its Complaint in Intervention within 90 days of filing the Government's Notice of Election to Intervene;
3. all other papers or Orders on file in this matter shall remain under seal; and
4. the seal shall be lifted on all matters occurring in this action after the date of this Order.



IN THE UNITED STATES DISTRICT COURT, FOR THE EASTERN DISTRICT OF PENNSYLVANIA FILED UNITED STATES OF AMERICA et al., rel f, AK - 8 2019 CHARLES STRUNCK, KATE BARKMAN, Olefk '3y Pe,>. Clerk Plaintiffs, v. Civil Action No. 12-CV-0175 QUESTCOR PHARMACEUTICALS, INC., FILED UNDER SEAL Defendant. ORDER The United States having intervened in this action, pursuant to the False Claims Act, 31 U.S.C. Â§ 3730(b)(4), the Court rules as follows: IT IS ORDERED that, 1. the relator's Fourth Amended Complaint, the Government's Notice of Election to Intervene, and this Order be unsealed; 2. the United States shall file its Complaint in Intervention within 90 days of filing the Government's Notice of Election to Intervene; 3. all other papers or Orders on file in this matter shall remain under seal; and 4. the seal shall be lifted on all matters occurring in this action after the date of this Order.

HCSC v. Mallinkrodt ARD LLC, Case No. RG20056354

Exhibit 2 to Declaration of Matthew S. Weiler

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**UNITED STATES OF AMERICA, et al., ex rel.
CHARLES STRUNCK, et al.,**

Plaintiffs,

v.

MALLINCKRODT ARD LLC.
(f/k/a Mallinckrodt ARD, Inc.;
f/k/a Questcor Pharmaceuticals, Inc.),

Defendant.

UNITED STATES OF AMERICA, et al., ex rel.
SCOTT CLARK,

Plaintiffs,

v.

MALLINCKRODT ARD LLC.
(f/k/a Mallinckrodt ARD, Inc.;
f/k/a Questcor Pharmaceuticals, Inc.),

Defendant.

: Civil Action No. 12-CV-0175

A TRUE COPY CERTIFIED FROM THE RECORD
 DATED: JUN - 4 2019
 ATTEST: Steve Tamas
 DEPUTY CLERK UNITED STATES DISTRICT COURT
 EASTERN DISTRICT OF PENNSYLVANIA

: Civil Action No. 13-CV-1776

UNITED STATES' COMPLAINT IN INTERVENTION

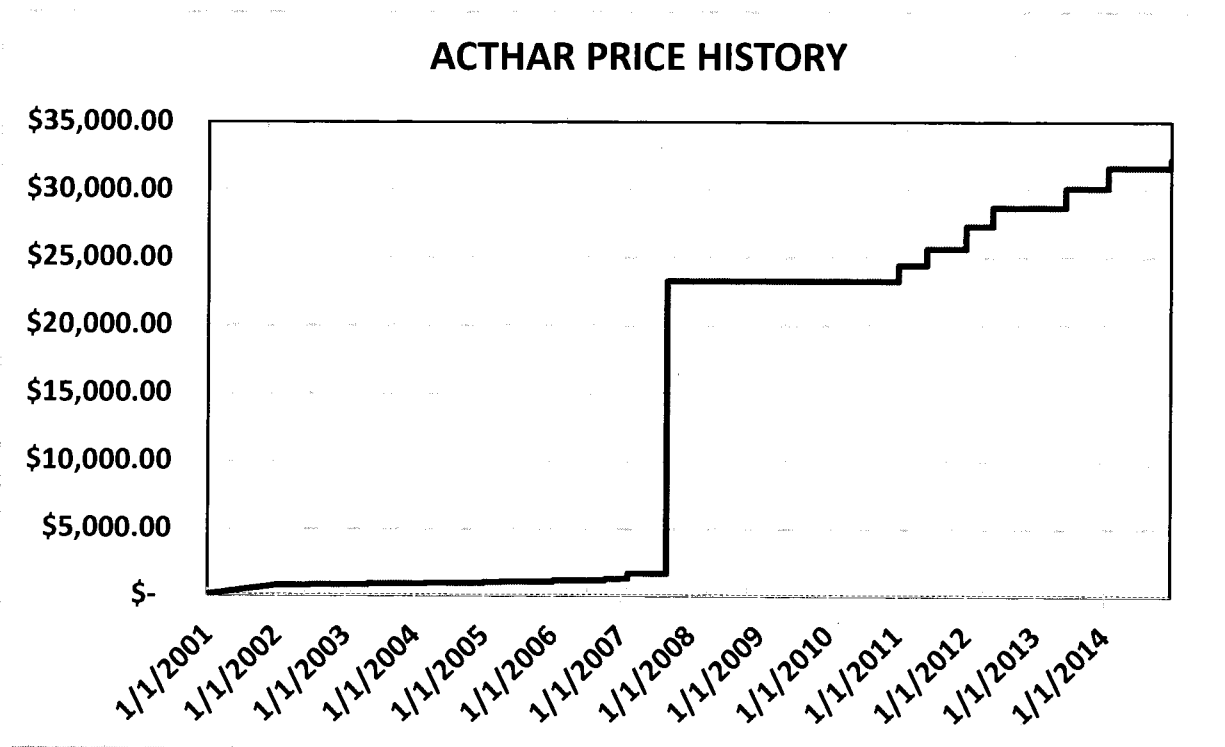
By notice to the Court on March 6, 2019, the United States of America intervened in the above-captioned cases. The United States alleges as follows:

INTRODUCTION

1. The United States of America (“United States”) brings this action against Defendant pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (“FCA”), seeking treble damages and civil penalties.

2. From 2010 through 2014 (“relevant time period”), Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD, Inc. and previously Questcor Pharmaceuticals, Inc.) (collectively “Mallinckrodt,” the “Defendant,” or the “Company”) knowingly paid illegal kickbacks in the form of copayment subsidies for its drug Acthar Gel (also referred to as H.P. Acthar Gel) (collectively “Acthar”). The scheme allowed the Company to continually raise Acthar’s price yet market it as “free” to patients and doctors, shifting the drug’s ever-increasing cost to Medicare. As a result of its conduct, Mallinckrodt caused the submission of millions of dollars in false Medicare claims for Acthar.

3. Mallinckrodt did not develop Acthar. The U.S. Food and Drug Administration (“FDA”) first approved Acthar in the 1950s, and Mallinckrodt acquired it in 2001. From the time of the acquisition until December 2014, Mallinckrodt raised Acthar’s per-vial price from approximately \$50 per 5 milliliter vial to over \$32,200 per vial:



4. Mallinckrodt knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations in multiple sclerosis, lupus, and rheumatoid arthritis. Mallinckrodt intended to overcome this difficulty and did so by making the drug “free” to patients by subsidizing their Medicare copayments. By doing so, Mallinckrodt could maintain the high price of Acthar to maximize its own sales revenues, but minimize the risk that the drug’s high price would impede doctors and patients from using it.

5. Mallinckrodt knew that paying copay subsidies to Medicare patients was illegal. To achieve the same end indirectly, Mallinckrodt paid copay subsidies through a foundation that Mallinckrodt used as a conduit to do so. At the foundation, called the Chronic Disease Fund (now d/b/a Good Days) (collectively “CDF”), Mallinckrodt designed supposed “patient assistance” funds that paid copays for Acthar only and then funded them through “donations,” knowing its money would be used on Acthar copays to the exclusion of other drugs. Mallinckrodt then sent Medicare patients to CDF in order to receive virtually guaranteed, Mallinckrodt-funded subsidies. The Company also obtained and used data about the number patients at CDF, the subsidies paid to them, and the amount of money Mallinckrodt needed to pay to keep covering their Acthar copays. Mallinckrodt financed the funds accordingly. Mallinckrodt also marketed the drug as “free” because of the copay funds it set up. Finally, the Company excluded financially-needy patients with Medicare coverage for Acthar from its own free product program in favor of sending those patients to CDF for copay subsidies to induce Medicare claims and, thus, generate a sale of the drug for Mallinckrodt.

6. Using the CDF Funds as a conduit to pay illegal copay subsidies was profitable for Mallinckrodt. For example, at a time when Acthar cost \$30,000, Mallinckrodt could spend

\$1,500 to subsidize a five percent Medicare copay knowing that it would reap as much as \$28,500 in sales revenue from that prescription.

7. Mallinckrodt's scheme circumvented the Congressional design of the Medicare system, which requires a copay, in part, to act as a market constraint against increasing drug prices. Instead, Mallinckrodt left American taxpayers to shoulder the drug's ever-increasing cost, while the Company reaped for itself the resulting profits.

JURISDICTION, VENUE, PARTIES

8. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

9. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

10. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) and because Defendant transacts business in this District.

11. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), and, specifically, its operating division, the Centers for Medicare & Medicaid Services ("CMS").

12. Relator Charles Strunck is an individual who resides in the State of New York. Relator Strunck was employed by Mallinckrodt from September 2010 until August 2011 as an Acthar sales specialist with responsibility for sales in the States of New York and Connecticut. Relator Lisa Pratta is an individual who resides in the State of New Jersey. Relator Pratta was employed by Mallinckrodt from September 2010 through June 17, 2017 as an Acthar sales specialist with responsibility for sales in New Jersey. On January 20, 2012, Relators Strunck and Pratta filed *United States, et al., ex. rel. Strunck v. Questcor Pharm., Inc.*, Civil Action No. 12-

175 (BMS) (E.D. Pa.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b).

13. Relator Scott Clark is an individual who resides in the state of Oregon. Mr. Clark was employed by Mallinckrodt from September 2010 until June 2012 as an Acthar sales specialist with responsibility for the State of Oregon. On April 4, 2013, Relator Clark filed *United States, et al., ex. rel. Clark v. Questcor Pharm., Inc.*, Civil Action No. 13-cv-01776 (BMS) (E.D. Pa.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b).

14. Defendant Mallinckrodt ARD LLC has its principal place of business at 1425 U.S. Route 206, Bedminster, NJ, 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and, prior to that, was named Questcor Pharmaceuticals, Inc. (“Questcor”).

15. Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt plc, an Irish public limited company. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014.

16. Questcor survived the merger as a wholly owned indirect subsidiary of Mallinckrodt plc and continued to market Acthar thereafter, until changing its name to Mallinckrodt ARD, Inc. on July 27, 2015.

17. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and continues to market Acthar under that name now.

18. Mallinckrodt has marketed Acthar in the United States at all relevant times for purposes of this complaint-in-intervention. Mallinckrodt conducts business nationwide.

LEGAL BACKGROUND

I. THE MEDICARE PART D PROGRAM AND COPAYS UNDER MEDICARE PART D

A. Medicare Part D

19. Congress established Medicare in 1965 to provide health insurance coverage for people aged sixty-five or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395 *et seq.*

20. Medicare is funded by the federal government and administered by CMS, which is part of the United States Department of Health and Human Services (“HHS”).

21. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. Under Medicare Part D, Medicare contracts with private entities, known as Part D Plan Sponsors, to administer prescription drug plans. *See* 42 C.F.R. § 423.4.

22. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. An individual is eligible to enroll in Medicare Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Medicare Part A or enrolled under Medicare Part B. *See* 42 C.F.R. § 423.30(a).

23. The Part D Sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D Sponsors, in turn, enter into subcontracts with pharmacies, or other “downstream entities,” to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

24. These entities submit claims to Part D plans that pay for the drug using funds provided by CMS from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

B. Medicare Part D Copay Obligations

25. By Congressional design, under the Medicare statute, a Part D beneficiary may be required to make a partial payment for the cost of these prescription drugs in the form of a “copayment,” “coinsurance,” or “deductible” (collectively “copays”). These copay obligations can be substantial for expensive medications and vary throughout the year, depending on a beneficiary’s total Part D covered expenses incurred that year up to that point. *See* 42 U.S.C. § 1395w-102. For example, after meeting an annual deductible (originally \$250 in 2006), the standard Part D benefit requires a 25 percent patient copay up to an “initial coverage limit” (originally \$2,250 in 2006). *Id.* at b(1)-(2).

26. After meeting the “initial coverage limit,” during all relevant times, patient copay obligations increased substantially prior to meeting an “annual out-of-pocket threshold” for the coverage year. This period exceeding the “initial coverage limit” and before crossing the “annual out-of-pocket threshold” is referred to as the “coverage gap.” *See* 42 U.S.C. § 1395w-102(b)(2)(D). For brand name drugs, the patient copay owed in the “coverage gap” was 100 percent through 2010, 50 percent in 2011 and 2012, and 47.5 percent in 2013 and 2014.

27. The financial thresholds for the “deductible,” “initial coverage limit,” and annual “out-of-pocket threshold” have increased each year since 2006 pursuant to a statutory and regulatory formula (from \$250, \$2,250, and \$3,600 respectively to \$310, \$2,850, and \$4,700 respectively by 2014).

28. Medicare Part D coverage for costs incurred after the “coverage gap”, *i.e.*, on costs incurred for the remainder of the benefit year above the “annual out-of-pocket threshold” (originally \$3,600 in 2006), is commonly referred to as “catastrophic coverage.”

29. Congress determined that patients owe a copay obligation in the “catastrophic coverage” phase equaling the greater of: 1) five percent of the prescription drug costs; or 2) a small fixed dollar amount (originally \$5 for brand name drugs in 2006). 42 U.S.C. § 1395w-102(b)(4). As a practical matter, a patient will owe a five percent copay in the “catastrophic coverage” phase of Part D for any expensive, brand name drug. As described below, the remaining costs are paid by a “reinsurance subsidy” from CMS (80 percent) and the Part D plans (15 percent).

30. These Medicare copays exist to encourage physicians and beneficiaries to be efficient consumers of federally reimbursed health care products, while also encouraging those manufacturing such products to price them based on market forces such as consumer sensitivity and competition. Manufacturers paying the Medicare copays of those seeking to buy their drug circumvent this congressionally designed check on health care costs. As the United States Department of Health and Human Services, Office of the Inspector General (“HHS-OIG”) has observed, drug manufacturers paying the Medicare Part D copays of patients taking their products “eliminat[e] a market safeguard against inflated prices.” HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005) (“2005 SAB”).

II. THE FALSE CLAIMS ACT

31. The FCA provides, in pertinent part, that any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

. . . is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

32. For purposes of the FCA, the terms “knowing” and “knowingly” mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

33. The FCA defines the term “claim,” in pertinent part, as

any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

Id. at § 3729(b)(2).

34. For purposes of the FCA, the term “material” means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Id.* at § 3729(b)(4).

III. THE ANTI-KICKBACK STATUTE

35. The Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are excessively costly, medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would “contribute significantly to the cost” of federal health care programs absent federal penalties as a deterrent. H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056.

36. The AKS was first enacted in 1972, and was strengthened in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148. In adopting and strengthening the AKS repeatedly, Congress sought to “strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs.” H.R. Rep. No. 95-393, at 1 (1977).

37. The AKS is a federal criminal statute that prohibits any person or entity from knowingly and willfully offering or paying anything of value (including money), directly or

indirectly, overtly or covertly, to any person to induce that person to purchase or refer federally-funded medical goods or services, including prescription drugs covered by Medicare.

38. Violation of the AKS is a felony and can also subject the perpetrator to criminal penalties, exclusion from participation in federal health care programs, and civil monetary penalties. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

39. In pertinent part, the Anti-Kickback Statute provides:

(b) Illegal remunerations . . .

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2).

40. The AKS defines remuneration to include anything of value, including “cash” and “in-kind” payments or rebates. 42 U.S.C. § 1320a-7b(b)(2). Money and other forms of financial subsidies that can be used to pay or waive Medicare copays constitute remuneration under the AKS.

41. The AKS defines a “Federal health care program” to mean “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government,” except for the health insurance

program for federal employees under 5 U.S.C. §§ 8901 *et seq.* 42 U.S.C. § 1320a-7b(f).

Medicare is a “Federal health care program” for purposes of the Anti-Kickback Statute.

42. The AKS provides that: “With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” 42 U.S.C. § 1320a-7b(h).

43. The AKS further provides that any Medicare claim “that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are per se false or fraudulent within the meaning of 31 U.S.C. § 3729(a). Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

44. Compliance with the AKS is material to the agency’s decision to pay a Medicare claim.

45. As set forth in more detail below, Mallinckrodt knowingly and willfully paid remuneration to Medicare patients to induce the patients to purchase Acthar by providing them with financial subsidies to satisfy the copayment obligations necessary to buy the drug (which were often significant for Medicare patients, because of the price Mallinckrodt set for Acthar). At least one purpose of the remuneration in the form of copay subsidies was to induce patients and doctors to use and purchase Acthar.

46. By providing kickbacks to induce prescriptions for and purchases of Acthar that were reimbursed by Medicare, Mallinckrodt knowingly caused false claims to be submitted to Medicare for Acthar.

FACTUAL BACKGROUND

I. BACKGROUND ON MULTIPLE SCLEROSIS, LUPUS, AND RHEUMATOID ARTHRITIS

A. Multiple Sclerosis

47. Multiple sclerosis (“MS”) is a central nervous system disease in which the body’s immune system attacks the body’s myelin nerve cell coating. MS can cause a variety of symptoms, which can increase in severity periodically.

48. MS “relapses,” “acute exacerbations,” or “flares” (collectively “MS exacerbations”) are temporary periods of increased disease activity in an MS patient, manifested by the worsening of existing MS symptoms or the onset of other MS symptoms. MS exacerbations are not a separate disease from MS.

49. The FDA has approved several medications for the long term treatment of MS patients, including medications to slow the accumulation of physical disability from the disease or to decrease the frequency of acute exacerbations. These medications are sometimes referred to as MS “disease modifying” drugs or therapies. Acthar is not a “disease modifying” drug or therapy for MS.

50. The FDA also has approved drugs for treatment of MS exacerbations, such as Acthar. A standard treatment for MS exacerbations includes administering methylprednisolone, a steroid, which can be administered intravenously (“IVMP”) or orally. Both IVMP and oral methylprednisolone are available in several brand name or generic forms. The drugs are significantly less expensive than Acthar.

B. Lupus

51. Systemic lupus erythematosus (“Lupus”) is an autoimmune disease in which the body’s immune system targets its own healthy cells. Lupus can damage the kidneys, brain, skin, joints, or other areas of the body.

52. Lupus patients can experience “flares” or “exacerbations” (collectively “Lupus exacerbations”), which are periods of increased disease activity and are characterized by worsening Lupus symptoms.

53. Lupus exacerbations are not a separate disease from Lupus.

54. A standard treatment for Lupus exacerbations includes the administration of steroids, which can be available in brand name or generic forms. The drugs are significantly less expensive than Acthar.

C. Rheumatoid Arthritis

55. Rheumatoid Arthritis (“RA”) is an inflammatory autoimmune disease in which the body’s immune system targets itself, including the joints. RA patients can experience “flares” or “exacerbations” (collectively, “RA exacerbations”), which are periods of increased disease activity and are characterized by worsening RA symptoms.

56. RA exacerbations are not a separate disease from RA.

57. A standard treatment for RA exacerbations includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

II. BACKGROUND ON ACTHAR GEL

58. Acthar is an adrenocorticotrophic hormone analogue that is injected either beneath the skin (subcutaneously) or into the muscle (intramuscularly), depending on its use.

59. The U.S. Food and Drug Administration approved Acthar for marketing in the United States in 1952, after the pharmaceutical division of a large meatpacking and food processing company invented the drug in 1948. Acthar's active ingredient is extracted from pig pituitary glands.

60. According to its FDA label, once injected, Acthar may stimulate the body to secrete certain hormones (such as cortisol and corticosterone). According to Mallinckrodt's website, "the exact way Acthar works is unknown," but it is "believed to work" by helping the body "produce its own natural steroid hormones" and by affecting the body's immune cells to have an "impact" on inflammation.

61. Acthar's FDA label contains an approval for the treatment of MS as follows: "Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease."

62. Acthar's FDA label also contains an approval for "Collagen Diseases," including Lupus. It is FDA-approved for treatment "[d]uring an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)."

63. Acthar's FDA label also contains an approval for "Rheumatic Disorders," "[a]s adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: [p]soriatic arthritis, [r]heumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), [a]nkylosing spondylitis."

64. In 2010, the FDA approved Acthar to treat a rare seizure disorder afflicting children called infantile spasms ("IS").

III. MALLINCKRODT ACQUIRED ACTHAR, RAISED ITS PRICE TO OVER \$23,000 PER VIAL, AND STOPPED MARKETING IT FOR MS

65. In July 2001, Mallinckrodt acquired worldwide rights to sell and manufacture Acthar from another drug company, Aventis Pharmaceuticals, Inc.

66. Mallinckrodt began to market Acthar in the third quarter of 2001 and initially increased its price from approximately \$50 per vial to nearly \$750 per vial. It quickly became the Company's main product, accounting for 94 percent of Mallinckrodt's net sales by the end of 2006.

67. During this time period, the majority of Acthar sales came from referrals for IS patients by pediatric neurologists, although the Company did promote Acthar to adult neurologists for use on MS patients as well. MS usage accounted for about one-third of Acthar referrals until 2007.

68. In 2007, Mallinckrodt adopted a so-called "orphan pricing strategy" that purportedly focused on positioning Acthar as a preferred therapy for IS, sharply increasing its price, and pivoting away from marketing Acthar for MS or other more common diseases.

69. On August 27, 2007, Mallinckrodt increased the cost of Acthar to over \$23,000 per 5 milliliter vial. This represented an increase of over 46,000 percent from Acthar's approximately \$50 price when Mallinckrodt acquired it six years earlier.

70. Mallinckrodt settled on this per-vial price because it wanted the new cost of an average Acthar regimen for IS to be approximately \$100,000.

71. In choosing this new per-vial price, Mallinckrodt initially believed that it had priced Acthar out of the MS exacerbation treatment market, which has many low-cost treatment options. The Company believed the new price of Acthar would "negate any business potential

Acthar had in MS.” Mallinckrodt terminated its MS sales force and dedicated remaining account representatives to work with IS prescribers.

72. By the end of 2007, Mallinckrodt’s net sales increased to \$49.8 million, from \$12.8 million the year before. As the Company expected, MS referrals declined to an all-time low of just eight vials in December 2007 (compared to an average of 250 vials per month prior to the 2007 price increase).

DEFENDANT’S FRAUD SCHEME

73. Mallinckrodt soon realized that it could generate significant revenue if it could successfully sell Acthar as an MS treatment at the new \$23,000 per vial price.

74. Mallinckrodt also knew that the new price was a barrier to those sales, given the wide availability of less expensive alternatives and the lack of scientific data showing that Acthar was more effective than those alternatives.

75. But Mallinckrodt soon determined that, if it subsidized Acthar copays, it could market the drug as “free” to doctors and patients, while payers such as Medicare absorbed the drug’s increased cost.

76. Rather than provide these illegal subsidies directly, Mallinckrodt routed them through a foundation, CDF. CDF is headquartered in Plano, Texas, and operates funds that receive payments from donors and uses those payments to pay copay subsidies to patients, including Medicare patients in this judicial district.

77. Mallinckrodt established funds at CDF and made payments to them, intending for all of its funding to be used to subsidize the copays for Acthar but no other drug.

78. Mallinckrodt then sent patients to CDF and actively tracked the status of every referral. Mallinckrodt made continued payments to the funds in amounts necessary to keep subsidizing the Acthar copays of patients the Company sent there.

79. As Mallinckrodt implemented this scheme, its Acthar sales and revenue grew significantly and Mallinckrodt believed the subsidies it routed through CDF were the “most motivating factor” to “[d]rive Acthar [p]rescribing” in the face of concerns about Acthar’s cost. With a proven method to negate these concerns, Mallinckrodt raised Acthar’s price to over \$32,000 per 5 milliliter vial by the end of 2014.

I. MALLINCKRODT REALIZED IT COULD INCREASE ITS ACTHAR PROFITS BY UNLAWFULLY SUBSIDIZING ACTHAR COPAYS

80. Not long after raising Acthar’s price to over \$23,000 per vial in 2007 and believing, at least initially, that it had priced itself out of the MS market, Mallinckrodt saw that the market potential of successfully selling Acthar as an MS treatment at the new price would be hundreds of millions of dollars. Mallinckrodt re-established a pilot MS sales force in 2008 to try to generate Acthar MS referrals at the new price.

81. Mallinckrodt knew that Acthar had many cheaper, effective competitors in the MS exacerbation treatment market. For example, according to Mallinckrodt, IVMP was “far and above [the] market leader in acute exacerbation therapy,” and “[t]he price of Acthar compared to the relative ease and convenience of a three-day, generic IVMP infusion . . . creates a significant barrier” with MS physicians. Mallinckrodt further knew that, while “the retail price for an average course of Acthar based upon the labeled 2-3 week dosing (2 vials) is approximately \$50,000,” the “standard treatment with IVMP [] ranges anywhere from \$400-\$1,200” and “this disparity in price is compounded by the lack of scientific evidence to support significant clinical

advantages in flare treatment.” Mallinckrodt also knew that, in some instances, low-cost, oral steroids were also “becoming an attractive option in the treatment of MS flares.”

82. Mallinckrodt also understood that, for some insurance plans, the over-\$23,000 price could lead to very high patient costs. Medicare Part D beneficiaries, in particular, could owe thousands of dollars in copays for one vial of Acthar while advancing through the deductible, initial coverage limit, and coverage gap. Even in the catastrophic coverage stage of Part D copays, Acthar patients would owe five percent of the drug’s cost (*i.e.*, more than \$1,150 per vial).

83. Mallinckrodt realized subsidizing patient copay obligations could overcome some doctor and patient cost concerns.

84. Mallinckrodt knew that it was illegal to subsidize Medicare copays directly, so it sought to accomplish the same result through a “copay assistance fund” that it designed, created, and used as a money conduit to pay patient copay subsidies for Acthar (but no other drug).

85. Mallinckrodt initially attempted this by providing funding to a foundation called the National Organization for Rare Disorders (“NORD”). In particular, Mallinckrodt hoped to use NORD to subsidize Acthar copays on a large scale (to match its ramped-up marketing efforts), and the Company wanted detailed data confirming that its payments were being spent on Acthar copays (and not other drugs).

86. Mallinckrodt did not think that NORD effectively served the Company’s purposes. In the spring of 2010, Mallinckrodt decided to switch from NORD and began to look elsewhere for an organization that, in Mallinckrodt’s opinion, better serve its desires. The individuals involved in making this determination included: 1) a Senior Manager of Specialty Distribution and Support Services in Mallinckrodt’s Reimbursement Division (“Reimbursement

Manager”); 2) a full time consultant that Mallinckrodt hired from an entity called BioSolutia to work with Mallinckrodt regarding NORD and other Acthar reimbursement issues (“BioSolutia Consultant”); 3) Mallinckrodt’s Vice President of Commercial Operations (“Commercial VP”); and 4) Mallinckrodt’s then-Executive Vice President and Chief Business Officer, whose title changed to Chief Operating Officer the next year (“Mallinckrodt’s COO”).

87. After discussions, in April and May 2010, these individuals agreed that the BioSolutia Consultant would contact CDF to discuss starting a new fund for Mallinckrodt to replace the copay fund at NORD.

II. MALLINCKRODT ESTABLISHES ITS ACTHAR COPAY CONDUIT AT CDF

A. The MS “Acute Exacerbation” Fund

88. On May 27, 2010, the BioSolutia Consultant emailed Mallinckrodt’s COO, Commercial VP, and Reimbursement Manager that: “As promised, I spoke with [the President of CDF] this morning and described our potential need and situation re: MS Exacerbation Copay Fund.” The BioSolutia Consultant explained that CDF already had a patient assistance fund for MS patients, but that CDF’s President “thought we would be able to comfortably define the fund as specific to MS exacerbation, as we’ve done at NORD, to prevent chronic MS med needs from tapping the funds.” This was important to Mallinckrodt because the Company did not want to make payments to a fund that might pay the copays of MS drugs other than Acthar.

89. Mallinckrodt’s COO responded to the BioSolutia Consultant the same day: “This sounds like a good possibility” and asked to schedule a meeting with CDF. The BioSolutia Consultant wrote back to CDF: “Thanks for discussing [Mallinckrodt]’s needs re: MS Exacerbation Copay Assistance fund with me today” and added that he would provide CDF with dates for an introductory meeting. He also explained that Mallinckrodt expected to pay an

increasing amount of Acthar Medicare copays going forward: “In 2009 the fund generated about \$450K in needs and in 2010 it is tracking about 20% above that since most are Med-D with percentage (specialty tier) copays.”

90. On June 1, 2010, after subsequent discussions with Mallinckrodt, CDF gave a presentation to Mallinckrodt’s COO and other employees demonstrating CDF’s operational “capabilities” to meet this ramped up demand. In an e-mail to Mallinckrodt’s Reimbursement Manager that evening, the BioSolutia Consultant noted that, after the presentation, Mallinckrodt’s COO viewed the choice between NORD and CDF as “Mom & Pop vs. WalMart.”

91. Within two weeks, Mallinckrodt decided that it needed a “WalMart” copay fund to operationalize its scheme on a larger scale. As Mallinckrodt’s COO wrote to Mallinckrodt’s CEO on June 18, 2010:

We have made the decision to move the co-pay programs to the Chronic Disease Fund from NORD. . . . In short, we are at the point where we have outgrown NORD’s “mom-and-pop” co-pay capabilities, and this change will give us a much better understanding of flow of funds and flexibility regarding how co-pay funds [*sic*] are made available.

92. At the same time, Mallinckrodt held discussions with CDF to finalize the establishment of the new “MS Acute Exacerbation Fund.” Mallinckrodt set up the fund for just patients with government insurance, such as Medicare Part D.¹

93. Mallinckrodt and CDF agreed that the MS Acute Exacerbation Fund would cover the copays of Acthar but not the copays of other drugs. For example, on July 9, 2010, CDF sent Mallinckrodt a “Program Spec[ification]” term sheet, making the Acthar-specific nature of the

¹ For patients with private insurance, Mallinckrodt had CDF open a separate Acthar “Private Fund” for Mallinckrodt to send private insurance patients to CDF to have Acthar copays paid. That fund also exclusively covered Acthar.

fund clear. The document, entitled “HPActhar_ProgramSpecs” stated that the “Product = H.P. Acthar Gel” for the “public” MS Acute Exacerbation Fund.

94. Mallinckrodt sent an executed copy of the donation agreement for the MS Acute Exacerbation Fund to CDF on July 14, 2010.

95. The MS Acute Exacerbation Fund agreement contained multiple statements that were known to be false at the time they were made. For example, the agreement stated the fund would provide financial assistance, including copay assistance, to “patients being treated for acute exacerbations of multiple sclerosis with any medically appropriate therapy[.]” In reality, and as Mallinckrodt intended and demanded, the MS Acute Exacerbation Fund paid copays for Acthar exclusively.

96. The donation agreement also falsely stated that CDF already operated “an assistance program for patients being treated for acute exacerbations of multiple sclerosis . . . [and Mallinckrodt] desires to provide [CDF] with a donation for [it].” At that time, CDF did not have such an assistance program; the fund was established at the behest of Mallinckrodt, and Mallinckrodt viewed the fund as its own.

97. The agreement also stated that the Program “eligibility criteria will be developed by the Board [of CDF] without consideration or input by Donor.” In fact, the decision that only Acthar patients were eligible was dictated by Mallinckrodt.

98. Key individuals at Mallinckrodt agreed and shared the view that the fund was established and controlled by Mallinckrodt and exclusively available to Acthar patients. For example:

- In an email from Mallinckrodt’s COO to CDF’s Senior Director of Operations on July 15, 2010—telling her to expect Mallinckrodt’s first payment the next day—Mallinckrodt’s COO wrote: “I have notified NORD’s President . . . that we have now

established co-pay funds at CDF to help address out [sic] expanding needs for patient support and monitoring of funding flows.” (Emphasis added.)

- On July 21, 2010, the BioSolutia Consultant wrote to several specialty pharmacies, copying the Mallinckrodt Reimbursement Manager, that “[Mallinckrodt] will be adding [CDF] as an administrator/source of funding for their copay assistance programs for Acthar.” (Emphasis added.)
- On October 19, 2010, the Reimbursement Manager wrote to the sales force again that: “Please be sure that your offices are aware of our Copay Assistance Program” and reminded them that “a key point to cover when discussing copay assistance” is that “[Mallinckrodt] established an Acute Exacerbations of Multiple Sclerosis ‘bucket’. As a result, Acthar patients needing copay assistance will not be using funds provided by the manufacturers of the disease modifying therapies.” (Emphases added.)
- On October 26, 2011, the Reimbursement Manager wrote to the Executive Director of CDF in an email titled “[Mallinckrodt] copay funds” to schedule a discussion about future payments to CDF and “operational things.” (Emphasis added.)
- On January 15, 2012, the Reimbursement Manager wrote to the Commercial VP about the need for more payments to CDF: “I anticipate a higher demand on our copay funds this month because most Med-D patients will need coverage for the donut hole because everything reset on January 1st.” (Emphasis added.)

99. On July 15, 2010, Mallinckrodt’s COO approved a wire transfer for \$150,000 from Mallinckrodt to CDF to fund the MS Acute Exacerbation Fund and Private Fund. CDF received the wire on July 16, 2010, and the MS Acute Exacerbation fund opened at that time. From this point through 2014, the MS Acute Exacerbation Fund paid Medicare copays for Acthar but not for any other drug.

100. Mallinckrodt sent patients to CDF via the Company’s “reimbursement hub” for Acthar, called the Acthar Support and Access Program (“ASAP”). Mallinckrodt controlled ASAP, which included a call-center that received referrals for Acthar from physician offices and patients. Mallinckrodt’s sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so the Company could track them. After a referral came in to ASAP, as

discussed in more detail below, ASAP provided patients with an “automatic offering” of copay assistance via CDF.

101. Although the new fund was ostensibly defined as limited to MS “Acute Exacerbation” patients to ensure that Mallinckrodt’s payments to it would not be used on other MS drugs that are prescribed for long-term disease treatment, Mallinckrodt never intended to place any such limitation on Acthar patients.

102. Instead, Mallinckrodt, via ASAP, referred Acthar patients to the fund regardless of whether they were using the drug for an acute exacerbation or on a long-term basis. Internally, Mallinckrodt referred to this longer-term use of Acthar in MS patients as “pulse maintenance” or “pulse” therapy.

103. Mallinckrodt acknowledged this to be an unapproved use of Acthar, took steps internally to identify which Acthar prescriptions were for such “pulse” treatments, and knew it accounted for a significant number of Acthar refills. As stated in an analysis of refill patterns prepared for the Commercial VP on October 24, 2011, for example: “Take a look at the attached spreadsheet. I think a significant percentage of refills are attributed to pulse like treatment.” Through the MS Acute Exacerbation fund, Mallinckrodt sometimes paid patients’ recurring copay subsidies for years’ or months’ worth of Acthar referrals.

104. As Mallinckrodt expanded its Acthar marketing beyond MS, it repeated this same scheme in two other areas: Lupus and Rheumatoid Arthritis.

B. The Lupus “Exacerbation” Fund

105. Mallinckrodt began planning to market Acthar for Lupus in mid-2011 and assumed that it needed to subsidize Medicare copays to induce sales of Acthar for Lupus as it

had for MS. Mallinckrodt thus set about to establish a purported Lupus “exacerbation” fund that the Company could use as a conduit to subsidize Lupus patients’ Medicare copays for Acthar.

106. On July 6, 2011, Mallinckrodt’s Reimbursement Manager wrote the COO:

After our recent discussions about lupus, it occurred to me that we will need to create copay fund at CDF for this disease state. It would make sense to start the fund with a minimal amount of money until we can determine the referral volume for that diagnosis. I’m not sure how soon we can expect to see a referral but we will want to have the fund in place as soon as we think there may be enough interest to generate a prescription. It would be easy to add this to our program so please let me know your thoughts on when we should contact CDF.

107. The COO responded: “It’s good to think ahead for sure. . . . [A]s long as we can set up a new fund quickly I don’t think there is any rush. Maybe you can discuss with [CDF] and tell [CDF] that at some point down the road we will probably start seeing lupus prescriptions so we can hear from them how quickly it can be set up.”

108. On Friday, September 2, 2011, the Reimbursement Manager wrote CDF: “We are moving into a new area, lupus, and we would like to set up a public [Medicare] fund for this disease state. How quickly can we do this . . . ?”

109. CDF’s Senior Director responded on the same day: “A public find [*sic*] takes me 24hours [*sic*] to set up. I will send over our agreement template. What is the name of the product?”

110. Mallinckrodt’s Reimbursement Manager responded the same day, stating:

The product is still Acthar😊

111. The Reimbursement Manager reported back to Mallinckrodt's COO the same day that "[CDF] can set up a copay fund for lupus with[in] 24 hours. She is going to send over a template agreement. We can have a fund established next week if you'd like."

112. The Reimbursement Manager replied to CDF via email on September 6, 2011 "let me know what we need to do in order to get this fund set up" and then again on September 12, 2011, "[c]an you help me out with this?" After further interaction with CDF, the Reimbursement Manager reported to the COO on September 20, 2011, that "[w]e are going to open a copay fund for Lupus," and said that calling it another "exacerbation" fund would be necessary to exclude other drugs from it. He wrote: "I was thinking of calling it something like 'Acute Exacerbation of Lupus Fund' so we don't open ourselves up to other drugs being used for maintenance therapy." He continued: "[CDF] said if we established the fund for exacerbations, Acthar patients that may be prescribed Acthar for maintenance could still get coverage."

113. The COO responded: "I am OK using the name you proposed but I would not want us to be limited in terms of what patients can enroll, given our very broad [FDA] label." He continued that the "only real maintenance drug is Benlysta" and that the fund should be named in such a way to "capture most of the use of Acthar but exclude most Benlysta use." "For example," the COO wrote, "our current MS fund is titled 'MS acute exacerbations', which allows Actahr [*sic*] patients to get covered but excludes Avonex, Copaxone, etc. patients."

114. CDF then prepared a contract for Mallinckrodt to establish the "Lupus Exacerbation" fund, and Mallinckrodt's COO signed it on October 31, 2011.

115. The Lupus Exacerbation Fund agreement contained false statements similar to those in the MS Exacerbation Fund agreement. It falsely stated that the fund would pay for "any

medically appropriate therapy,” and that the fund’s eligibility criteria were developed without any donor’s “input.” It also falsely stated that CDF already had such a fund.

116. Two days later, on November 2, 2011, Mallinckrodt wired an initial \$25,000 payment to CDF. The fund then opened.

117. From this point through 2014, the Lupus Exacerbation fund paid the Medicare copays of Acthar but no other drug.

118. Again, as it did with the MS Acute Exacerbation fund, Mallinckrodt knew a significant portion of its Acthar referrals for lupus were for longer-term, non-acute treatment. In fact, because “maintenance” treatment for Lupus was on-label, Mallinckrodt planned to market Acthar for this use.

119. According to Mallinckrodt, the Lupus “pulse maintenance opportunity is similar to the pulse-maintenance approach in MS” and posed a “[l]arge per patient revenue opportunity” for the Company. As of August 2012, Mallinckrodt estimated that 40 percent of its “[t]arget [p]opulation” for Lupus would be maintenance patients and, by November 2012, observed that while the “[e]xpected dosage for each [Lupus] flare is 1.5 vials,” the “[v]ials per script [would] gradually increase[] to account for maintenance therapy[.]”

120. Mallinckrodt sent longer-term patients to the so-called Lupus “exacerbation” fund via ASAP, as it did with MS. The fund sometimes paid for continuous Acthar refills that went on for months or years.

C. The RA “Exacerbation” Fund

121. In the summer of 2012, Mallinckrodt started marketing Acthar as a treatment for Rheumatoid Arthritis and soon determined that it needed another Acthar-only fund at CDF to pay the Medicare copays of these patients, too. On September 13, 2012, just three hours after

receiving questions from ASAP about whether copay subsidies would be available for Acthar RA referrals, Mallinckrodt's Reimbursement Manager emailed CDF's Senior Director and a CDF Quality Analyst asking them to schedule a call with him, the COO, and the Commercial VP to "to discuss setting up a public fund for RA," and noting that "[w]e'd like work with you on what to call this[.]" CDF scheduled the call for 10:30 AM the next morning, September 14, 2012.

122. Even though the fund had not opened yet, CDF started planning for Mallinckrodt's referrals to it. Shortly after noon on September 14, 2012, the CDF Quality Analyst wrote to all CDF call center employees (who received referrals over the phone from ASAP) that: "All, [i]f we have any referrals/requests for assistance with RA and the patient is being treated with Acthar, please get all of the patient's information and notate their account. . . . Advise the patient that we will contact them back in regards to the assistance. Then email me and the [Senior Director] with the ID number for the patient. Under no circumstances should you say or indicate that we do not have a fund open at this time . . . I need each of you to email me back regarding this communication indicating that you have read and understood the above message."

123. Meanwhile, Mallinckrodt prepared for the fund's opening on its end. On September 15, 2012, the BioSolutia Consultant reported back to ASAP that he expected the fund to be opened shortly: "As described by [the Reimbursement Manager] during yesterday's status call, . . . in about a week [he] expects to have a fund established to be able to also provide [copay subsidies] for patients with [Medicare Part D]" for RA referrals.

124. Mallinckrodt was now accumulating Acthar RA referrals where the sale could not be completed without copay assistance. On September 18, 2012, the BioSolutia Consultant

emailed Mallinckrodt's Reimbursement Manager, "[a]ny new info on Med-D RA fund? Cases holding." The Reimbursement Manager replied "No word yet."

125. The same day, Mallinckrodt's Reimbursement Manager wrote to CDF: "Sorry to be a pest but I'm at a meeting with [the COO] and [the Commercial VP] and they are constantly asking me if I've heard any information from you guys." CDF had responded that CDF needed to confer with its own counsel before proceeding further. On September 21, 2012, the Reimbursement Manager wrote again: "[The COO] and [the Commercial VP] are getting really anxious about this fund because we have several patients that are in need of funding and waiting for drug. Can you please update me?" Later that day CDF agreed to "open the fund under the category of Exacerbation of Rheumatoid Arthritis[.]"

126. Mallinckrodt's Reimbursement Manager emailed Company rheumatology sales force personnel several hours later that "I am happy to announce that we just established a fund at CDF for RA patients. The fund is titled 'Exacerbation of Rheumatoid Arthritis' . . . [T]his is a great addition to our offerings. What this means is that we can now offer RA patients with [Medicare Part D] copay assistance." From this point forward, the RA Exacerbation Fund paid the Medicare copays of Acthar but no other drug.

127. Based on reports and tracking it received on refill patterns from ASAP, Mallinckrodt knew that some of the Acthar referrals it made to CDF's RA "Exacerbation" fund were actually for long-term use. As with MS and Lupus, Mallinckrodt sent these patients to the RA "Exacerbation" fund via ASAP and, through it, paid copay subsidies for sometimes months' or years' worth of Acthar refills.

III. MALLINCKRODT SENT MEDICARE PATIENTS TO THE FUNDS IT CREATED AT CDF TO RECEIVE ACTHAR COPAY SUBSIDIES

128. Shortly after establishing the MS Acute Exacerbation fund, and continually as it established the Lupus and RA Exacerbation funds, Mallinckrodt directed ASAP to send to CDF any Medicare patient who needed a copay subsidy to buy Acthar.

129. On July 15, 2010, the same day he sent the executed MS Acute Exacerbation fund contract to CDF, the Mallinckrodt COO wrote to the BioSolutia Consultant and the Reimbursement Manager to “ensure that gets implemented at the hub” (*i.e.*, ASAP). Within a month, this was complete. On August 13, 2010, the Reimbursement Manager wrote to Mallinckrodt’s COO that “[The BioSolutia Consultant] and I have instructed ASAP to send all copay patients to CDF and they are being handled without delay.”

130. Mallinckrodt initially directed ASAP to proactively offer copay assistance to any patient with Acthar copays in excess of \$200 but later reduced that threshold to \$150 to reduce the likelihood of Mallinckrodt “losing some referrals” absent an “automatic offering” of Acthar copay assistance.

131. As the Reimbursement Manager announced to the sales force on June 25, 2012:

Based on feedback from you and your managers, we have evaluated our current business rule of automatically offering copay assistance. Our current threshold for ASAP to proactively ask the patient if they need assistance with their copay is \$200 and **several of you suggested that we lower that amount because there are concerns about losing some referrals where the patient does not receive an automatic offering of copay assistance. Effective today, ASAP will begin proactively offering copay assistance to all patients with copays greater than \$150.** Keep in mind that patients needing assistance with smaller copay amounts will still be referred to CDF. We will monitor how this change impacts cases over the next several months and evaluate if a further reduction is necessary.

(Emphasis added).

132. Through this automated process that Mallinckrodt coordinated, Mallinckrodt filled the funds at CDF with patients the Company sent there itself. Mallinckrodt's ASAP program referred over 98 percent of the patients who received copay subsidies from the MS, Lupus, or RA "Exacerbation" funds at CDF.

133. Mallinckrodt also knew that virtually all of the patients it sent to CDF would receive copay subsidies for Acthar. As early as August 2010, Mallinckrodt's Reimbursement Manager assured a regional sales manager that: "Almost every patient that requests assistance will be approved, with the exception of very wealthy families." Mallinckrodt maintained this expectation of virtually guaranteed copay subsidies throughout the time period, as CDF confirmed for Mallinckrodt that it was approving almost every patient the Company sent there.

IV. MALLINCKRODT EXCLUDED MEDICARE PATIENTS FROM ITS FREE DRUG PROGRAM

134. During the same time period that Mallinckrodt sent Acthar patients to CDF to receive Medicare copay subsidies, the Company also retained NORD to operate a "Patient Assistance Program" ("PAP") that offered free Acthar to patients who met certain financial criteria and could not afford the drug's high price. ASAP also sent certain patients to NORD for that purpose.

135. But Mallinckrodt intentionally did not send Acthar patients with Medicare or other insurance coverage for the drug to the NORD PAP. Instead, Mallinckrodt sent those patients to CDF where they received copay subsidies to cover their costs and triggered insurance reimbursement for Acthar. Mallinckrodt also required patients to appeal insurance coverage denials of Acthar before referring them to the PAP. According to Mallinckrodt, patients "[m]ust exhaust appeal options after denials" and "[i]f we **exhaust** appeal options, patient will be referred to [PAP]." (Emphasis in original.)

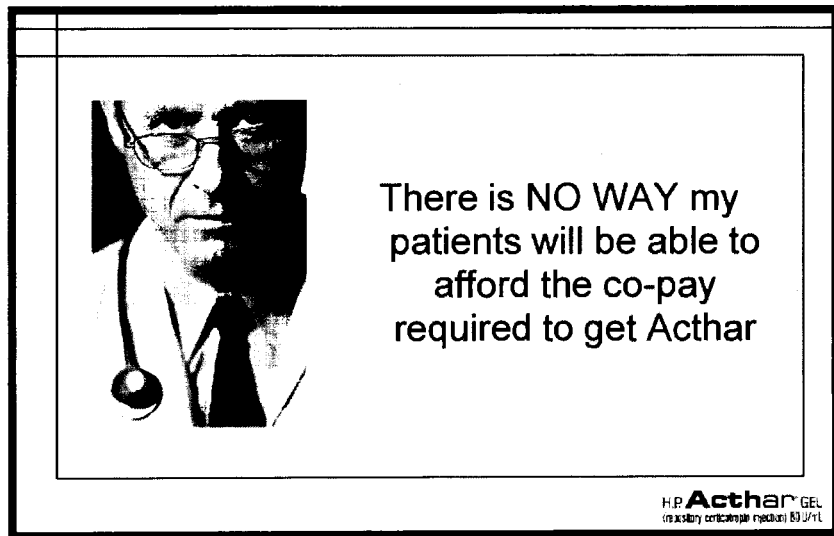
136. In other words, whenever possible, Mallinckrodt sought to cause Medicare claims to be submitted for Acthar so that Mallinckrodt could get paid from a sale of the drug as opposed to giving it away for free through the NORD PAP. As the BioSolutia Consultant wrote to the Reimbursement Manager on November 17, 2010: “We’re in the ‘sell more Acthar now business’ not the give more Acthar now.”

V. MEANWHILE, MALLINCKRODT MARKETING ACTHAR AS FREE TO DOCTORS AND THEIR PATIENTS

137. Mallinckrodt marketed guaranteed copay assistance to physicians and patients as a way to neutralize concerns about the price and to induce sales and Medicare reimbursement. This began immediately after establishing the MS Acute Exacerbation Fund at CDF and continued throughout the relevant time period.

138. For example, on August 4, 2010, the Reimbursement Manager provided all regional sales managers with “talking points to use with [their] teams” on how to sell Acthar using copay assistance at CDF. He wrote that the “[m]essaging to [doctors]” should be “we offer copay assistance” and that “patients that need assistance will [] get approved over the phone in most cases.”

139. The same month, Mallinckrodt developed talking points and trainings for the sales force to evade objections to Acthar’s high price and to sell Acthar using the promise of copay subsidies. The very first talking point read: “DO NOT APOLOGIZE FOR THE PRICE.” The training directed sales representatives to “[r]eview [the] co-pay coverage program” with prescribers who expressed concern about the drug’s price. A set of Mallinckrodt training slides visualized anticipated objections about high copays this way:



The slides instructed the sales force to address this objection by telling doctors that, “[i]f a patient is unable to afford their co-pay, we offer an excellent co-pay coverage program” and “when co-pay is covered (in virtually all cases) it is for 100% of the co-pay.” (Emphasis added). According to the training, “the process is fast.”

140. Mallinckrodt’s Reimbursement Manager also emailed all sales representatives on October 19, 2010 with a “Tip of the Week” message to emphasize the importance of marketing Acthar as zero-cost to most patients. He stated: “Please be sure that your offices are aware of our Copay Assistance Program. It is important that the MD’s and nurses are aware of this program and understand it enough to explain it to their patients.”

141. Mallinckrodt meanwhile conducted extensive market research to confirm that these methods were effective. For example, Mallinckrodt commissioned a market study of neurologists to examine Mallinckrodt’s concern that “as a consequence of the price increase and the loss of goodwill physicians may be switching away from Acthar to alternative therapies.” The study reported as a “bottom line” that there is “pricing angst in MS” and that many MS physicians “consider [Acthar] to have a very poor value in terms of efficacy vs cost.” It also

reported that potentially high patient copays for Acthar concerned MS physicians: of the MS physicians surveyed, 25 percent reported not prescribing Acthar in the last twelve months because the “patient copay is too high” after the price increase.

142. Mallinckrodt internalized the study’s findings in its sales plan for Acthar. Addressing the question of “What Will Increase Prescribing?”, Mallinckrodt’s plan noted that “copay support” is “important” because “cost to the patients is a key concern.”

143. Mallinckrodt took steps to ensure that the sales force executed the Company’s sales strategy of marketing Acthar as free due to virtually guaranteed copay subsidies via CDF. For example, on June 9, 2011, an Acthar Product Manager at corporate headquarters (the “Product Manager”) sent an email to the sales force managers asking that they survey the sales representatives in each of their respective regions and ask three questions: 1) whether the representatives messaged co-pay assistance; 2) what percentage of the time did they discuss co-pay assistance; and 3) “how do [they] message co-pay assistance for Acthar?” Their answers, reported back through the sales managers to the Product Manager and the Reimbursement Manager, confirmed that the sales force had been using copay assistance for Acthar as a “selling tool,” as the Company intended. The sales representatives’ responses included:

- “I use co-pay [*sic*] assistance program as a selling tool.”
- “Call it co-pay coverage. If your [patient] hits donut hole in Med D and has huge co-pay or has a \$50 co-pay that they can’t afford, [Mallinckrodt] will cover it for them.”
- “I make sure that the nurse presents the co-pay assistance info to the patient to prevent them from jumping to any wrong conclusions if the co-pay is high.”
- “[F]or higher copays, patients can get co-pay assistance through a fund set up by [Mallinckrodt] through [CDF].”

- “99% of the time; Most every call when the cost to the patient is discussed; I discuss it more frequently when there is a pushback on the copays []; Almost every call.”
- “Do not let cost be the reason why you wouldn’t RX Acthar.”
- “I reference co-pay assistance to physicians, ancillary staff and billing. I talk about it 100% of the time. It is part of all calls . . . [Mallinckrodt] provides co-pay assistance for patients in need covered at 100%.”
- “Most every call especially when the cost to the patient is discussed. I state . . . [if] for any reason the copay is more than \$200 the patient will automatically get copay assistance and will get the ACTHAR for free. I also state that if the patient expresses concern on the amount of the copay under \$200 they can still qualify for copay assistance and get it for free.”
- “I discuss that no co-pay amount is too small for [Mallinckrodt] to cover . . . Cost is the issue in my territory. I have to talk about the copay assistance program with my accounts.”
- “[Mallinckrodt] generally covers whatever insurance does not[,] so[] no concern for patient having to bear the financial burden for cost of Acthar.”
- “Many of our Acthar patients do not pay a co-pay because of our extensive co-pay assistance program.”

144. When one sales representative indicated that she was not clear on the details of the Acthar “bucket” Mallinckrodt established at CDF, the Mallinckrodt Product Manager tried to justify her confusion to the Reimbursement Manager, noting that, “to be fair though, I would admit I have a lot to learn about this too. Maybe we could talk about the exact details sometime so I can be a pro too.” In an e-mail on June 17, 2011, the Reimbursement Manager rejected this explanation:

No need to add “To be fair” to this email. You weren’t trained like the sales force so it’s not surprising that you aren’t an expert in this area. **Our reps are out there selling the most expensive drug on the planet and one of them didn’t know about our copay bucket for AE of MS. That’s a shocker and probably makes her less effective when trying to get new MDs to write.**

(Emphasis added). The Product Manager responded:

Good point. You're the best! 😊

145. Mallinckrodt's sales force continued to promote guaranteed Acthar copay subsidies via CDF in this manner, with the intent to induce Medicare Part D claims throughout the relevant time period.

VI. MALLINCKRODT CONTINUED TO MAKE PAYMENTS TO CDF AND UNDERSTOOD THAT ITS "DONATIONS" SUBSIDIZED ACTHAR COPAYS EXCLUSIVELY

146. Mallinckrodt made continued payments to CDF to keep subsidizing Acthar copays through the MS "Acute Exacerbation," Lupus "Exacerbation" and RA "Exacerbation" funds throughout the relevant time period. Knowing that each fund covered Acthar exclusively, Mallinckrodt intended to keep these financial conduits functioning smoothly by fully funding them to subsidize the copays of all the Acthar patients Mallinckrodt sent to CDF.

147. Mallinckrodt monitored this by receiving detailed financial reports from CDF, called "Program Reports," containing information about how many patients were enrolled in the fund, how much the fund had already paid out, and how much had been allocated to enrolled patients. The reports also stated the percentage of patients approved to receive copay subsidies, the average copay amount paid by the fund, the total number of resulting drug "dispenses" (broken out by new dispenses vs. refills), and the remaining fund balance.

148. Because these funds paid Acthar copays only, all of these reported metrics were specific to Acthar. This gave Mallinckrodt the ability to monitor its fund balances and confirm the amount of future Mallinckrodt-to-CDF payments necessary to keep paying Acthar copay subsidies smoothly.

149. For example, on August 13, 2010, shortly after the MS Acute Exacerbation Fund opened, the Reimbursement Manager wrote to Mallinckrodt's COO: "I'll be receiving updated reports from [CDF] later this afternoon so I can keep an eye on the fund balances[.]" The COO replied: "Good. Let's keep a close eye on usage and we can replenish as necessary." On May 22, 2012, the Reimbursement Manager wrote to the Commercial VP: "Here is the latest funding balance at CDF. I am setting up a call with [CDF] so we can walk through these numbers to see where we stand for actual dollars. The amount of funding for patients has dramatically increased due to volume and the Med-D copay amounts during Q1."

150. Mallinckrodt also compared this information to internal information it received in reports from ASAP to check that the amounts CDF reported as necessary for future Acthar subsidies were, in fact, necessary for that purpose. The reports from ASAP included a daily "Case Review" report, via the BioSolutia Consultant, that identified: the status of each Acthar referral received; confirmation that specific patients had been referred to and accepted by CDF; and confirmation that these patients' Acthar vial(s) had been purchased and shipped as a result. The reports also identified whether referrals to CDF (and approvals by CDF) were for Medicare Part D patients.

151. This information, combined with the CDF reports, confirmed for Mallinckrodt that CDF was using Mallinckrodt's "donations" to pay the Acthar Medicare copays of the same patients Mallinckrodt sent to CDF. If there were questions about whether a request from CDF for more funding was justified, Mallinckrodt double-checked the request against this information to confirm it.

152. For example, on October 28, 2011, the Reimbursement Manager wrote the COO that CDF had informed him that it needed more funding for the MS Acute Exacerbation fund,

Lupus Exacerbation fund and the Private Fund, and that CDF had “promised me a report by next Wednesday that will show us the amount of real dollars paid out for each fund so we know exactly where we sit as the year comes to an end.” The COO responded: “I assume you have reviewed the pattern of funding and utilizing of money for these funds and that this level of funding is appropriate for each, or are we waiting for [CDF’s] report to do so?” The Reimbursement Manager replied: “I have been carefully watching the volume of copay assistance requests for each disease state and I reviewed the approximate fund balances with [CDF] last week. The funding requested by CDF is appropriate for each disease state and we continue to see a high demand for copay assistance for MS patients[.]” The COO replied “OK, I’ll approve these and forward to accounting for payment.”

153. On September 1, 2012, Mallinckrodt and CDF entered into a “Service Agreement Amendment” to their July 15, 2010 “agreement to administer a Copay Assistance Program” for Acthar (collectively, “Amendment”). The Amendment provided that Mallinckrodt would provide “bulk donations” to CDF “with the intention of funding all programs in which H.P. Acthar Gel is on formulary” and that CDF would “distribute the donations . . . as needed” internally to ensure uninterrupted copay subsidies for Acthar by each fund. From that point forward, CDF styled its “donation request” letters to Mallinckrodt as seeking money for the “H.P. Acthar Gel Programs,” *i.e.*, not for a specific fund.² Mallinckrodt made payments on this basis through December 2013, always paying the amounts CDF requested for the “H.P. Acthar Gel Programs.”

² Prior to this, Mallinckrodt would sometimes “roll over” funds that it had already donated to the Private Fund at CDF into the other funds paying Acthar Medicare copays, upon notice from CDF that these funds were running low.

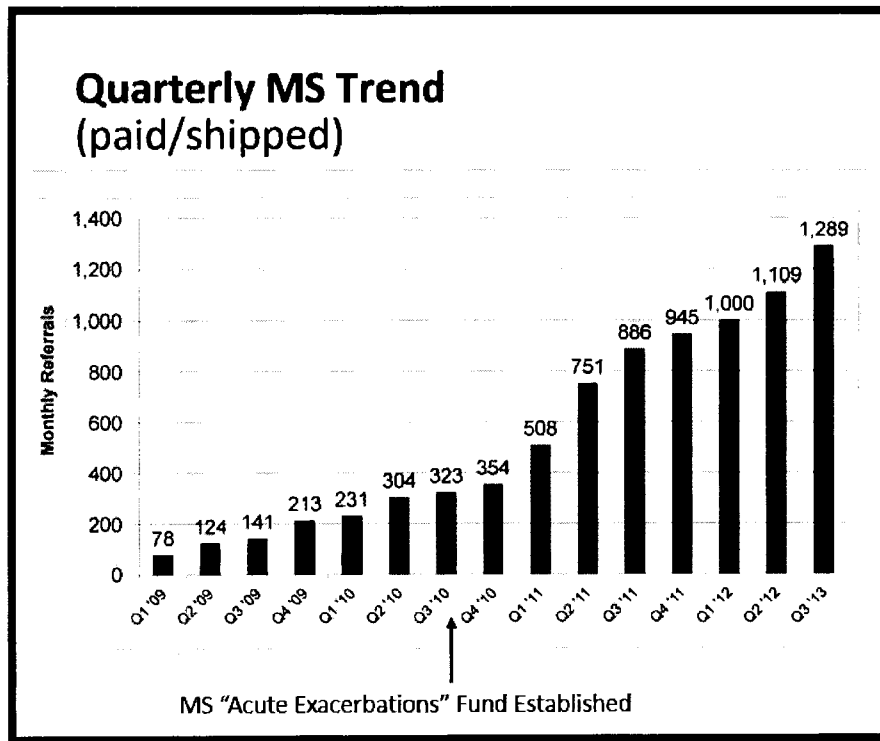
154. In December 2013, CDF decided to close Mallinckrodt's funds but was willing to subsidize already-enrolled patients for another year if Mallinckrodt continued to make payments to CDF to do so. Mallinckrodt continued to subsidize Acthar copays using CDF through 2014 and made additional payments to the "H.P. Acthar Gel Programs" for that purpose.

155. From 2010 through 2014, Mallinckrodt made the following payments to CDF for the MS Acute Exacerbation fund, Lupus Exacerbation fund, RA Exacerbation fund, or the "H.P. Acthar Gel Programs" (including the Private Fund):

Date	Amount	Date	Amount	Date	Amount	Date	Amount	Date	Amount
07/21/10	11,000.00	01/13/11	150,000.00	02/03/12	100,000.00	01/18/13	1,200,000.00	01/10/14	1,004,600.00
07/21/10	117,000.00	01/13/11	150,000.00	02/03/12	100,000.00	02/25/13	883,000.00	02/11/14	801,100.00
09/17/10	75,000.00	04/08/11	150,000.00	04/06/12	500,000.00	04/04/13	1,550,000.00	03/03/14	367,000.00
Total	203,000.00	04/08/11	150,000.00	06/14/12	1,000,000.00	04/24/13	341,500.00	04/01/14	117,500.00
		05/23/11	150,000.00	07/10/12	800,000.00	05/14/13	897,000.00	05/20/14	360,500.00
		05/23/11	150,000.00	07/24/12	750,000.00	06/26/13	500,000.00	06/13/14	117,000.00
		07/13/11	150,000.00	08/29/12	850,000.00	06/27/13	590,500.00	08/08/14	232,000.00
		07/13/11	150,000.00	10/10/12	850,000.00	07/26/13	1,165,000.00	09/11/14	52,000.00
		08/29/11	150,000.00	11/14/12	850,000.00	10/04/13	957,000.00	10/16/14	52,000.00
		08/30/11	150,000.00	12/14/12	900,000.00	10/07/13	987,300.00	11/14/14	52,000.00
		11/02/11	150,000.00	Total	6,700,000.00	10/08/13	200,000.00	12/12/14	52,000.00
		11/02/11	150,000.00			10/25/13	902,000.00	Total	3,207,700.00
		11/02/11	25,000.00			12/18/13	1,354,000.00		
		Total	1,825,000.00			Total	11,527,300.00		

VII. AS MALLINCKRODT'S SCHEME WORKED, IT INCREASED ACTHAR'S PRICE AND PROFITS

156. After Mallinckrodt established the co-pay conduit at CDF, the Company achieved significant growth in Acthar MS sales and corporate revenue. For example, as demonstrated below, Acthar MS sales nearly quadrupled between the third quarter of 2010 (when Mallinckrodt established the MS "acute exacerbation" fund, as annotated) and the third quarter of 2013.



157. Mallinckrodt believed that covering Acthar copays through CDF was a key driver for these sales. In a business plan for 2013, for example, Mallinckrodt observed that “more financial assistance” was the single most significant “motivating factor” that would “increase likelihood of using Acthar” and address “concern[] about the cost” of the drug:

Ways to Drive Acthar Prescribing

More financial assistance continues to be the most motivating factor in increasing HCP prescribing of Acthar, showing that they are still concerned about the cost.

158. Not long after establishing the MS “acute exacerbation” fund at CDF, Mallinckrodt executed a sustained pattern of subsequent price increases. On December 4, 2010, Mallinckrodt’s CEO circulated a presentation pitching that Mallinckrodt was a “sales company,

not a development company” and could position itself to “dominate” certain niche markets for other “devastating, difficult-to-treat conditions” with “higher prices”:

QCOR Could Dominate a Niche

- Devastating, difficult-to-treat medical conditions
 - Lower competition level, higher prices permitted
- Profitable, building shareholder value
 - Returns substantially greater than cost of capital
- Science-driven sales
 - Sales company, not a development company

159. Although the Company’s total revenues had already increased approximately ten times over since 2006 (the year before the price increase to \$23,000), from 2010 to 2014, Mallinckrodt implemented further price increases as it expanded its copay conduit scheme at CDF. On January 3, 2011 Mallinckrodt raised Acthar’s price to over \$24,430 per vial. Under six months later, it raised the price again to over \$25,600 per vial. In December 2011, it raised the price to over \$27,300 per vial. In May 2012, it raised the price to over \$28,680 per vial. In June 2013, it raised the price to over \$30,100 per vial. In January 2014, it raised the price to over \$31,600 per vial. And, in December 2014 it raised the price to over \$32,200 per vial.

160. Mallinckrodt's revenue and profits increased substantially after increasing Acthar's price further. For example, the Company reported net sales of Acthar of over \$761 million by the end of 2013.

**MALLINCKRODT KNOWINGLY AND WILLFULLY VIOLATED THE AKS BY
PAYING ACTHAR MEDICARE COPAYS**

161. Mallinckrodt knowingly and willfully violated the AKS by paying illegal Acthar copay subsidies as described above to induce prescriptions and sales of Acthar reimbursed by Medicare.

**I. MALLINCKRODT KNEW THAT THE AKS PROHIBITS THE COMPANY
FROM PAYING ACTHAR MEDICARE COPAYS**

162. Mallinckrodt had knowledge and understanding of the AKS and its prohibition on paying remuneration with an intent to induce purchases or referrals. Mallinckrodt also had knowledge and understanding of the False Claims Act and its prohibition on submitting, or causing to be submitted, false claims to federal health care programs, including Medicare. Mallinckrodt further knew that claims resulting from kickbacks are not payable by Medicare and that it was illegal to offer Medicare beneficiaries inducements in the form of copay subsidies. Mallinckrodt trained its employees on these laws, including the key individuals who interacted with CDF, and they understood that it would be unlawful for Mallinckrodt to pay patients' Acthar Medicare copays.

163. Mallinckrodt compliance training stated that "[c]ompliance with various laws and regulations that impact interactions with health care professionals . . . , customers, or others who may purchase, prescribe, [or] influence the use of Mallinckrodt's products" includes compliance with "Healthcare fraud & abuse; Anti-kickback statutes, [and the] False Claims Act." Regarding the "Kickback Prohibition," the training warned that "[e]mployees must never provide anything

of value (money or in-kind) as an inducement or a reward for purchasing, prescribing, using, or recommending Mallinckrodt's product(s)." Another Mallinckrodt compliance training specified that the "Anti-Kickback Laws" "prohibit payments intended to induce someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs."

164. Mallinckrodt's corporate policies also reflected Mallinckrodt's knowledge that such payments are illegal and that causing the submission of false claims to Medicare violates the False Claims Act.

165. Mallinckrodt's "Reimbursement Assistance" policy stated that:

Under the False Claims Act, it is a violation of law for anyone to knowingly make, or cause others to make, false statements or claims to the federal government. Misuse of a diagnosis code, or any other inaccuracy submitted in any of the information submitted in a claim for reimbursement from a Federal Health Care Program could be challenged as a false claim.

166. The same policy specified that it is a violation of the AKS to offer "Reimbursement Assistance"—which includes "referrals to financial assistance programs or patient assistance programs"—to induce the use or purchase of Acthar. According to the policy, "the Anti-Kickback Statute prohibits providing Reimbursement Assistance" to someone "who is 1) involved in the provision of health care services; and 2) in a position to purchase, lease, recommend, use, arrange for the purchase or lease of, or influence the purchase or lease of, [Mallinckrodt's] products" to "induce him or her to purchase, recommend, use, or arrange for the purchase or prescription of [Mallinckrodt] products."

167. The Mallinckrodt employees interacting with CDF understood the law, as explained in these policies and trainings. These employees knew that Mallinckrodt could not legally pay Medicare copays for Acthar. For example, on June 24, 2010, the Reimbursement

Manager emailed the Commercial VP: “I don’t think we can reimburse patients directly if they have a government payer (Med-D or Medicaid HMO).” Mallinckrodt’s Commercial VP responded: “You are right if it’s Medicare part D.”

168. Mallinckrodt’s employees also understood that the pharmaceutical industry in general viewed paying Medicare Part D copays as illegal under the AKS. Trade publications they circulated shared this view. For example, on February 11, 2010, the BioSolutia Consultant emailed Mallinckrodt’s Reimbursement Manager an email entitled “copay articles,” and attached several articles, including a January 2010 publication from “Pharma Exec” (the industry website at www.pharmaexec.com, which describes itself as offering “Commercial Insight for the C-Suite”). The publication stated that copay subsidies from manufacturers to patients “have emerged as the preferred solution to preserving market share” but that “co-pay offsets are an illegal inducement for Medicare Part D beneficiaries.” The email also attached a *Wall Street Journal* Article from July 2009 entitled “Drug Makers Criticized for Co-Pay Subsidies” that stated: “Even as U.S. lawmakers seek new ways to rein in health-care spending, drug companies are quietly circumventing a proven tool for controlling prescription-drug costs: insurance co-payments.” The article noted that drug companies don’t pay copay subsidies for Medicare Part D patients “out of a concern” that doing so “could violate the federal anti-kickback law.” The next day, The Reimbursement Manager forwarded the articles to the Commercial VP, writing “[a]ttached are some articles [the BioSolutia Consultant] pulled regarding copay subsidies. I sent you the Pharma Exec article last month so you may [have] already seen that one.”

169. Nevertheless and despite knowledge that its payment of copays directly to Medicare Part D beneficiaries would violate the AKS, Mallinckrodt designed the MS, Lupus, and RA “Exacerbation” funds at CDF as conduits to accomplish the very same result.

II. MALLINCKRODT KNEW THAT HHS-OIG WARNED DRUG COMPANIES AGAINST USING FOUNDATIONS AS CONDUITS TO PAY MEDICARE COPAYS

170. For over 20 years, HHS-OIG has been authorized by Congress to provide guidance to the health care industry to prevent fraud and abuse. *See* The Health Insurance Portability and Accountability Act (“HIPAA”) of 1996, Public Law 104-191 § 201; 42 U.S.C. § 1320a-7c. To further this goal, and pursuant to this authority, HHS-OIG issues industry-wide guidance and advisory opinions about industry practices or arrangements that pose risks under anti-fraud laws such as the AKS.

171. Since at least 2005, just after Medicare Part D’s enactment but prior to the first coverage year (2006), HHS-OIG has issued industry wide guidance concerning the practice of drug companies subsidizing the copays of Medicare patients.

172. Mallinckrodt knew that HHS-OIG warned drug companies against paying the Medicare copays owed for their own drugs, and against using foundations as conduits to accomplish the same result, because doing so created a risk of AKS liability.

A. HHS-OIG Has Long Warned That Drug Companies Paying the Medicare Copays of Their Own Products Implicates The AKS And Facilitates Price Increases

173. In 2005, HHS-OIG issued industry-wide guidance advising that drug companies paying Medicare patient’s Part D copays (either directly or indirectly through a manufacturer’s patient assistance program) “pose a heightened risk of fraud and abuse under the [AKS].” *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, *70,624 (Nov. 22, 2005) (<https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf>) (“2005 SAB”). In particular, HHS-OIG advised that, in its view, such subsidies would “be squarely prohibited by the [AKS], because the

manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product.” 2005 SAB at 70,625. HHS-OIG further expressed the concern that this practice would present “all the usual risks of fraud and abuse associated with kickbacks” and could facilitate inflated prescription drug prices: “[w]e are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices.” 2005 SAB at 70,626.

174. Moreover, HHS-OIG cautioned that “[copay] subsidies can be very profitable for manufacturers,” because a drug’s sale price exceeds the amount of the copay subsidy. *Id.* This provides “additional incentives for abuse.” *Id.*³ HHS-OIG also cautioned that “pharmaceutical manufacturers may seek to improperly maximize these profits by creating sham ‘independent’ charities to operate [a Patient Assistance Program]” or “by colluding with independent charity programs to ensure that the manufacturer’s contributions only or primarily benefit patients using its products[.]” 2005 SAB at 70,626.

B. HHS-OIG Has Long Warned Drug Companies Against Using Foundations As Conduits To Accomplish the Same Result

175. Since at least 2005, HHS-OIG has also warned drug companies against using third-party foundations as mere conduits to pay Medicare copays. To avoid a potential risk of AKS liability, “the independent charity [patient assistance program] must not function as a conduit for payments by the pharmaceutical manufacturer to patients.” 2005 SAB at 70,627.

³ HHS-OIG issued a supplemental special advisory bulletin in 2014 reiterating these and other concepts from the 2005 SAB. *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120, 31,122 (May 30, 2014) (<https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf>) (“2014 SAB”) (“the ability to subsidize [copays] for their own products may encourage manufacturers to increase prices”).

176. HHS-OIG has also warned drug companies against attempting to influence supposedly independent charities into creating “funds” dedicated to the drug companies’ own products. HHS-OIG advised that creating “funds” defined in reference to the symptoms (or severity of symptoms) of a disease increases the risk of fraud and abuse by increasing the likelihood that drug company donors can earmark their “donations” to their drugs, and thereby create a conduit.

[W]e are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. **For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases.** This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs. **To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories, and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.**

2005 SAB at 70,627 (emphasis added).

177. HHS-OIG has also identified other indicia that may expose a drug company to potential AKS liability, such as exerting “any direct or indirect influence” over the foundation; or “solicit[ing] or receiv[ing] data from the charity that would facilitate . . . correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.” 2005 SAB at 70,626.

178. In 2006, HHS-OIG issued Advisory Opinion 06-10 to CDF, which incorporated these safeguards into its terms. (Sept. 14, 2006) (“CDF Advisory Opinion”) (<https://www.mygooddays.org/oig/AdvOpn06-10A.pdf>).

179. Mallinckrodt knew about HHS-OIG's guidance on these AKS risks. For example, the "donation agreements" Mallinckrodt signed with CDF referenced the importance of complying with "all applicable laws, statutes, rules and regulations," including "the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)" and also highlighted the "policies of the [HHS-OIG]," including the 2005 SAB. Mallinckrodt also received a copy of CDF's Advisory Opinion.

III. MALLINCKRODT IGNORED HHS-OIG'S WARNINGS ABOUT THE TYPE OF CONDUCT THAT WOULD VIOLATE THE AKS

180. Mallinckrodt ignored these concerns and engaged in conduct that HHS-OIG specifically warned was high-risk under the AKS.

181. Mallinckrodt did not avoid influencing CDF's creation of the MS, Lupus, and RA "exacerbation" funds. Rather, Mallinckrodt insisted that CDF create each new fund for Mallinckrodt, when Mallinckrodt needed each fund to support the Company's Acthar marketing efforts.

182. Mallinckrodt also insisted that these funds be narrowly defined in reference to symptoms of each disease, rather than supporting all drugs that treat each disease, in a bid to favor Acthar over other drugs. Mallinckrodt knew that "exacerbations" of MS, Lupus, and RA were not distinct diseases, but rather were references to each diseases' symptoms and/or their severity. For example, Mallinckrodt's 2010 Acthar business plan defined "relapses of MS" as the "periodic, sudden worsening of symptoms" in MS patients and video on Mallinckrodt's website today describes MS relapses as "an exacerbation of MS symptoms." Mallinckrodt insisted on these narrower symptom funds to help make sure its drug Acthar would be covered, to the exclusion of others, even when Acthar's FDA label was broader than the fund definition.

183. Mallinckrodt also received data that allowed it to correlate its payments to these funds with the number of Acthar prescriptions those payments subsidized. This enabled

Mallinckrodt to monitor the “usage” of its payments to CDF and keep paying CDF in amounts necessary to keep subsidizing the Acthar copays of the patients it sent there via ASAP.

184. In sum, knowing that paying Acthar Medicare copays was illegal and knowing that HHS-OIG had cautioned that using a foundation as a conduit to pay them instead posed serious AKS risk, Mallinckrodt did just that so it could market the drug as “free” and have Medicare absorb the drug’s ever-increasing cost.

MALLINCKRODT CAUSED
THE SUBMISSION OF MATERIALLY FALSE CLAIMS TO MEDICARE

185. Mallinckrodt’s conduct caused the submission of false claims to Medicare as a result of its AKS violations.

I. MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS UNDER MEDICARE PART D

186. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy (or submit it to a mail order specialty pharmacy) to be filled.

187. When the patient submits the prescription, the Medicare copay is due from the patient to complete the purchase of the drug and have the pharmacy fill the prescription by dispensing it to the Part D beneficiary.

188. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim to the beneficiary’s Part D Sponsor, which, in turn, submits an electronic record of the claim, called a Prescription Drug Event (“PDE”), to CMS. After dispensing the drug, the pharmacy receives reimbursement from the CMS-funded Part D Sponsor for the portion of the drug cost not paid by the Part D beneficiary at the point of sale.

189. The PDE contains many specific representations regarding this Medicare prescription drug claim, including the patient's name, service provider of the drug, the prescriber of the drug, the name of the drug, and the quantity dispensed to the patient. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

190. Generating and submitting PDE claims data is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors to reimburse them for qualified drug coverage that they provide to Medicare beneficiaries. Generating and submitting PDE data is a condition of payment for CMS's provision of Medicare funds to Part D Plan sponsors. *See* 42 C.F.R. § 423.322.

191. CMS pays Part D Plan Sponsors based upon these PDEs in various ways. For example, CMS gives each Part D sponsor advance monthly payments to cover, among other things, the Part D Plan Sponsor's direct CMS subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor) and estimated reinsurance subsidies (to account for CMS's anticipated 80 percent subsidy of the "catastrophic coverage" costs that will be incurred for all enrollees). *See id.* §§ 423.315, 423.329. At the end of the payment year, CMS then reconciles the advance payments paid to each Part D Sponsor with the actual costs the sponsor has incurred, as documented by PDE data. In this reconciliation process, CMS uses the PDE claims data submitted by the Part D Sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D that year. In the case of the federal government's 80 percent reinsurance subsidy for catastrophic costs, for example, if CMS determines that it underpaid the sponsor, it will make up

the entire difference.⁴ The payments made by CMS to the Part D sponsor — which in turn fund the provision of prescription drugs provided to beneficiaries at each drug dispensing event — come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

192. Part D Plan Sponsors must comply with “[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, et seq.), and the anti-kickback statute (§ 1127B(b)) of the Act.” 42 C.F.R. § 423.505(h)(1). Any “downstream” or “related” entities that Part D Plans subcontract with (including pharmacies dispensing medication) must also comply with these, and any other, contractual obligations of the Part D Plan, *see* 42 C.F.R. § 423.505(i)(3)(iii), and separately comply with all applicable federal laws, regulations, and CMS instructions. *See id.* § 423.505(i)(3)(iv).

193. CMS regulations require Part D Plan Sponsors and related “downstream” entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the health care products or services reflected therein. *Id.* § 423.505(k).

II. THE VIOLATIONS BY MALLINCKRODT WERE MATERIAL TO THE PAYMENT DECISION

194. Compliance with the AKS is a material condition of payment by Medicare.

⁴ CMS also uses PDE data to determine risk-sharing amounts owed by CMS to the plan or (if a plan significantly overestimated its non-catastrophic costs in its bid) owed by the plan to CMS. These risk-sharing amounts involve calculations based on whether and to what degree a plan’s allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

195. The centrality of the AKS to the claims payment decision is demonstrated by the fact that Congress has determined that any Medicare claim “that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g).

196. Entities submitting claims to Medicare are subject to mandatory exclusion from Medicare by HHS-OIG if criminally convicted of an AKS violation, *see, e.g.*, 42 U.S.C. § 1320a-7(a)(1), and subject to permissive exclusion if HHS-OIG determines that the provider “has committed an act” described in the AKS, 42 U.S.C. § 1320a-7(b)(7).

197. The AKS is a criminal statute specifically designed to preventing fraud on federal healthcare programs such as Medicare and prevent excessive costs to the Medicare program resulting from all forms of illegal inducements.

198. HHS-OIG has made clear that compliance with the AKS is material. It has also specifically provided guidance on its views of the risks inherent in drug companies paying copay subsidies to induce purchases of (and Medicare reimbursement for) their own drugs as potentially implicating the AKS, whether done directly or indirectly through a foundation. In particular, HHS-OIG has warned that drug company copay subsidies present “all the usual risks of fraud and abuse associated with kickbacks.” HHS-OIG has voiced repeated concern that these subsidies eliminate a “market safeguard against inflated [drug] prices” and expose the Medicare program to higher costs as a result. HHS-OIG has elaborated at length on the types of safeguards that may be put in place to avoid the risk of an AKS violation.

199. The United States regularly enforces the AKS and pursues FCA liability based on underlying violations of the AKS. In particular, it has pursued matters against drug companies like Mallinckrodt for conduct like that alleged here.⁵

200. The conduct by Mallinckrodt undermined the core concerns of the AKS — in particular, preventing excessive costs to Medicare resulting from illegal copay subsidies that facilitate high drug costs and push the financial burden of those costs to Medicare and the American taxpayer.

201. Mallinckrodt's conduct was sustained and systemic. It lasted over multiple years and involved thousands of claims submitted to Medicare. After a first successful attempt to create and use a funds for its own ends of subsidizing copays for Acthar patients, the course of conduct was repeated twice more for other funds also designed to enrich Mallinckrodt at the

⁵*Drug Maker United Therapeutics Agrees to Pay \$210 Million to Resolve False Claims Act Liability for Paying Kickbacks* (December 20, 2017) (<https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>)

Drug Maker Pfizer Agrees to Pay \$23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks (May 24, 2018) (<https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>)

Drug Maker Actelion Agrees to Pay \$360 Million to Resolve False Claims Act Liability for Paying Kickbacks (December 6, 2018) (<https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying>)

Three Pharmaceutical Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations (April 4, 2019) (<https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid>)

Two Pharmaceutical Companies Agree to Pay a Total of Nearly \$125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations (April 25, 2019) (<https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid>)

expense of the Medicare program. The kickbacks at issue here were for millions of dollars in total and were not insignificant.

202. Compliance with the regulatory requirement that the PDE data submitted to CMS is “true, accurate, and complete” is an express condition of payment under the Medicare Part D Program.

203. The submission of PDEs is essential to the functioning of the Part D Program, the singular purpose of which is to provide coverage for drug products for the Medicare population. The accuracy of the information contained in each PDE for each patient determines how much payment will be made by Part D for that particular prescription.

204. The scheme alleged here resulted in thousands of PDEs being submitted to Part D over a period of multiple years.

III. SAMPLE FALSE ACTHAR CLAIMS

205. Through the scheme described above, Mallinckrodt provided illegal copay subsidies for over 2,600 Acthar prescriptions to induce Medicare-reimbursed purchases of the drug, resulting in millions of dollars of false claims to Medicare during the relevant time period.

206. Throughout the time period where Mallinckrodt used CDF as a conduit to pay these illegal Acthar copay subsidies, patients used these subsidies at pharmacies to purchase Acthar prescriptions, and the pharmacies submitted claims to Medicare Part D sponsors seeking Medicare reimbursement for those prescriptions. These false claims are documented in PDE data. Moreover, Part D Plan Sponsors, in turn, submitted these false PDE data to CMS as the basis for payments from the federal government based upon the expenses incurred for these illegally subsidized Acthar prescriptions.

207. Prescription Drug Event data attached as Exhibits 1 and 2 demonstrate representative examples of false claims for Acthar prescriptions that were the subject of Mallinckrodt's illegal copay subsidies and reimbursed by Medicare. Each line item on these exhibits represents a distinct Prescription Drug Event reflecting a false Medicare claim for Acthar (*i.e.* a Medicare-reimbursed purchase of Acthar by a Medicare beneficiary to fill an Acthar prescription using a copay subsidy). In each instance, the drug is identified as Acthar by both its "National Drug Code" ("NDC Code") and its common name (in the "NDC Code Description") from the PDE data. In each line item, the PDE data also shows the Medicare Part D Beneficiary who received the drug, reported here in the "Bene Name" field (using a de-identified value for purposes of this exhibit).

208. In each line item, the "Date From Claim" column represents the date of service for the Medicare claim, *i.e.*, when the beneficiary purchased the Medicare-covered Acthar prescription from a pharmacy using the copay subsidy, as reported in the PDE data. The pharmacy then dispensed the units of Acthar reported in the Units Quantity Dispensed ("Units Quan Disp") column of the PDE data to the beneficiary. Acthar "units" are measured in milliliters and Acthar is sold in 5 milliliter vials. Accordingly, each multiple of 5 reported in this column represents one vial of Acthar dispensed for that claim.

209. For each line item, the "Date Processed" column represents the date Medicare processed and paid its share of the claim according to the PDE data. The reported Medicare cost of the prescription is reflected in the following PDE data fields: Amount Below Out-Of-Pocket Threshold ("Amt Below OOPT") and Amount Above Out-Of-Pocket Threshold ("Amt Above OOPT"). AMT Below OOPT refers to total costs for that prescription considered to be below the "catastrophic coverage" threshold for that benefit year. AMT Above OOPT represents the

portion of the drug cost considered to be in the “catastrophic coverage” benefit phase, and subject to the Medicare Part D reinsurance subsidy.

210. For each line item, the PDE data field “Pharm ID” represents a code corresponding to the pharmacy that dispensed the prescription, and the PDE data field “Presc ID” represents a code corresponding to the referring physician for the prescription (both reported using a de-identified value for purposes of this exhibit).

211. Exhibit 1 reflects 79 representative example false claims for Acthar prescriptions that Medicare reimbursed on behalf Patients AA, AB, and AC, who Mallinckrodt sent (via ASAP) to the MS Acute Exacerbation, Lupus Exacerbation, and RA Exacerbation funds, respectively, to receive Mallinckrodt’s Acthar copay subsidies.

212. Exhibit 2 reflects an additional 42 representative example false claims for Acthar prescriptions that Medicare reimbursed on behalf of the indicated patients residing in this judicial district, all of whom Mallinckrodt sent to CDF to receive Mallinckrodt’s Acthar copay subsidies.

213. All 121 of these sample false claims were submitted to Medicare for reimbursement and made the specific representations for each prescription described above, including: the identity of the beneficiary, drug, pharmacy and referring physician; the Medicare claim’s date of service and date Medicare processed the claim; the Medicare drug cost above and below the “out-of-pocket” threshold for each prescription; and the units of Acthar dispensed to the beneficiary for each prescription.

214. Exhibits 3 and 4 show the illegal copay subsidy amounts paid by Mallinckrodt for each sample false claim identified in Exhibits 1 and 2, respectively. Mallinckrodt paid, via CDF, the copay subsidy amounts reflected in the “Acthar Copay Subsidy Amount Paid For Claim” column (through the fund indicated by the “Fund” column) for each claim referenced in the

“Corresponding Sample False Claim No.” column, to induce each Medicare reimbursed-purchase of Acthar. These payments occurred on the same date as the “Date From Claim” field reported in the PDE data for each claim and were paid to the same Medicare beneficiary reported on each claim.

215. These copay subsidy amounts (and the funds through which Mallinckrodt paid them) show each illegal copay subsidy paid for each claim based upon CDF records.

216. The claims did not disclose that the patient received illegal remuneration to induce the purchase of the drug in violation of the AKS.

THE ACTHAR CLAIMS ALLEGED HERE ARE FALSE CLAIMS

217. Mallinckrodt knowingly and willfully paid remuneration to Medicare patients to induce the patients to purchase Acthar by providing them with financial subsidies to satisfy the copayment obligations necessary to buy the drug.

218. Mallinckrodt knowingly caused the submission of false claims for reimbursement to Medicare in each instance in which it provided a patient with a copay subsidy through CDF for Acthar.

219. The claims are per se false or fraudulent as a matter of law. 42 U.S.C. § 1320a-7b(g).

220. The claims are also false because the PDE data and the specific representations therein fail to disclose a violation of a requirement material to the agency’s payment decision, namely the AKS.

221. The PDE data was not true, accurate, and complete because it did not disclose a violation of the AKS. The PDE data for each claim was a false record that Mallinckrodt caused to be used to pay the false claims alleged herein.

222. The representations of compliance with the AKS made by the Part D Sponsor and downstream entities were false because the claims resulted from an illegal kickback. The representations were false records that Mallinckrodt caused to be used to pay the false claims alleged herein.

COUNT I
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1)(A))

223. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

224. By virtue of the acts described above, Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A); that is, Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for Acthar that were tainted by illegal kickbacks.

225. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendant's conduct.

226. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

COUNT II
(False Claims Act: False Records Material To A False or Fraudulent Claim)
(31 U.S.C. § 3729(a)(1)(B))

227. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

228. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements, namely, false claims, false statements in PDEs, and false statements about compliance with the AKS, all of which were material to false or fraudulent claims that were submitted to the United States and paid and approved by the Medicare program for Acthar that were tainted by illegal kickbacks, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

229. Payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendants' statements and actions.

230. By reason of the false or fraudulent records or statements, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

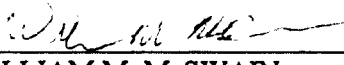
- I. On Count I under the False Claims Act against Defendant, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.
- II. On Count II under the False Claims Act against Defendant, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.
- III. All other and further relief as the Court may deems just and proper.

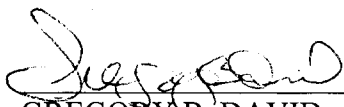
The United States hereby demands a jury trial on all claims alleged herein.

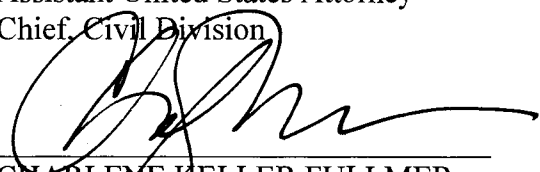
Dated: June 4, 2019


Respectfully submitted,

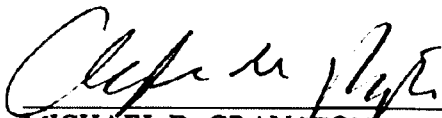
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EXHIBIT 1

Sample False Claim No.	NDC Code	NDC Code Description	Bene Name	Date From Claim	Units Quan Disp	Date Processed	Amt Above OOPT	Amt Below OOPT	Pharm ID	Presc ID
1	63004773101	ACTHAR HP	AA	08/09/2012	5	09/05/2012	\$ 31,287.17	\$ -	Pharmacy 4	MD 02
2	63004773101	ACTHAR HP	AA	10/03/2012	5	10/10/2012	\$ 31,287.17	\$ -	Pharmacy 4	MD 05
3	63004773101	ACTHAR HP	AA	10/19/2012	5	10/23/2012	\$ 31,287.17	\$ -	Pharmacy 4	MD 05
4	63004773101	ACTHAR HP	AA	11/13/2012	5	11/21/2012	\$ 31,287.17	\$ -	Pharmacy 4	MD 05
5	63004773101	ACTHAR HP	AA	11/23/2012	5	12/10/2012	\$ 31,287.17	\$ -	Pharmacy 4	MD 05
6	63004773101	ACTHAR HP	AA	12/28/2012	5	01/26/2013	\$ 31,287.17	\$ -	Pharmacy 1	MD 02
7	63004871001	H.P. ACTHAR	AA	01/30/2013	5	09/16/2013	\$ 29,288.91	\$ 1,998.26	Pharmacy 4	MD 02
8	63004871001	H.P. ACTHAR	AA	02/26/2013	5	03/08/2013	\$ 31,287.17	\$ -	Pharmacy 1	MD 02
9	63004871001	H.P. ACTHAR	AA	03/22/2013	5	04/26/2013	\$ 31,287.17	\$ -	Pharmacy 4	MD 01
10	63004871001	H.P. ACTHAR	AA	04/26/2013	5	05/15/2013	\$ 31,287.17	\$ -	Pharmacy 1	MD 02
11	63004871001	H.P. ACTHAR	AA	05/14/2013	5	09/16/2013	\$ 31,287.17	\$ -	Pharmacy 4	MD 02
12	63004871001	H.P. ACTHAR	AA	06/14/2013	5	06/21/2013	\$ 31,537.14	\$ -	Pharmacy 1	MD 01
13	63004871001	H.P. ACTHAR	AA	06/28/2013	10	11/12/2013	\$ 63,072.78	\$ -	Pharmacy 4	MD 02
14	63004871001	H.P. ACTHAR	AA	07/29/2013	5	11/12/2013	\$ 31,537.14	\$ -	Pharmacy 4	MD 01
15	63004871001	H.P. ACTHAR	AA	08/12/2013	5	08/23/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 01
16	63004871001	H.P. ACTHAR	AA	09/04/2013	5	09/16/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 01
17	63004871001	H.P. ACTHAR	AA	09/23/2013	5	10/01/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 01
18	63004871001	H.P. ACTHAR	AA	10/21/2013	5	11/12/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 02
19	63004871001	H.P. ACTHAR	AA	10/29/2013	5	11/12/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 02
20	63004871001	H.P. ACTHAR	AA	11/04/2013	5	11/12/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 02
21	63004871001	H.P. ACTHAR	AA	11/12/2013	5	11/22/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 02
22	63004871001	H.P. ACTHAR	AA	12/02/2013	5	12/09/2013	\$ 31,175.70	\$ -	Pharmacy 3	MD 02
23	63004871001	H.P. ACTHAR	AB	09/12/2013	5	09/23/2013	\$ 26,024.31	\$ 4,848.69	Pharmacy 2	MD 04
24	63004871001	H.P. ACTHAR	AB	09/30/2013	5	10/21/2013	\$ 30,873.00	\$ -	Pharmacy 2	MD 04
25	63004871001	H.P. ACTHAR	AB	10/17/2013	5	11/05/2013	\$ 30,873.00	\$ -	Pharmacy 2	MD 04
26	63004871001	H.P. ACTHAR	AB	11/11/2013	5	11/21/2013	\$ 30,873.00	\$ -	Pharmacy 2	MD 04
27	63004871001	H.P. ACTHAR	AB	11/25/2013	5	12/05/2013	\$ 30,873.00	\$ -	Pharmacy 2	MD 04
28	63004871001	H.P. ACTHAR	AB	12/10/2013	5	12/23/2013	\$ 30,873.00	\$ -	Pharmacy 2	MD 04
29	63004871001	H.P. ACTHAR	AB	12/30/2013	5	01/06/2014	\$ 30,873.00	\$ -	Pharmacy 2	MD 04
30	63004871001	H.P. ACTHAR	AB	01/16/2014	5	01/23/2014	\$ 23,750.93	\$ 7,122.07	Pharmacy 2	MD 04
31	63004871001	H.P. ACTHAR	AB	02/04/2014	5	09/17/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
32	63004871001	H.P. ACTHAR	AB	02/25/2014	5	09/17/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
33	63004871001	H.P. ACTHAR	AB	03/18/2014	5	09/17/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
34	63004871001	H.P. ACTHAR	AB	04/03/2014	5	09/17/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
35	63004871001	H.P. ACTHAR	AB	04/23/2014	5	09/17/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
36	63004871001	H.P. ACTHAR	AB	05/06/2014	5	05/22/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
37	63004871001	H.P. ACTHAR	AB	05/20/2014	5	06/07/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
38	63004871001	H.P. ACTHAR	AB	06/04/2014	5	06/23/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
39	63004871001	H.P. ACTHAR	AB	06/26/2014	5	07/23/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
40	63004871001	H.P. ACTHAR	AB	07/16/2014	5	07/31/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
41	63004871001	H.P. ACTHAR	AB	07/31/2014	5	08/18/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
42	63004871001	H.P. ACTHAR	AB	08/18/2014	5	10/09/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
43	63004871001	H.P. ACTHAR	AB	09/04/2014	5	10/14/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
44	63004871001	H.P. ACTHAR	AB	09/25/2014	5	10/14/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
45	63004871001	H.P. ACTHAR	AB	10/20/2014	5	11/18/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
46	63004871001	H.P. ACTHAR	AB	11/13/2014	5	12/02/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
47	63004871001	H.P. ACTHAR	AB	12/04/2014	5	12/23/2014	\$ 32,416.65	\$ -	Pharmacy 2	MD 04
48	63004871001	H.P. ACTHAR	AB	12/22/2014	5	01/07/2015	\$ 33,066.50	\$ -	Pharmacy 2	MD 04
49	63004871001	H.P. ACTHAR	AC	07/01/2013	5	07/27/2013	\$ 27,826.09	\$ 3,757.10	Pharmacy 3	MD 03
50	63004871001	H.P. ACTHAR	AC	07/17/2013	5	07/30/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
51	63004871001	H.P. ACTHAR	AC	08/20/2013	5	09/04/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
52	63004871001	H.P. ACTHAR	AC	09/04/2013	5	09/19/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
53	63004871001	H.P. ACTHAR	AC	09/24/2013	5	10/03/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
54	63004871001	H.P. ACTHAR	AC	10/10/2013	5	10/21/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03

Sample False Claim No.	NDC Code	NDC Code Description	Bene Name	Date From Claim	Units Quan Disp	Date Processed	Amt Above OOPT	Amt Below OOPT	Pharm ID	Presc ID
55	63004871001	H.P. ACTHAR	AC	10/28/2013	5	11/13/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
56	63004871001	H.P. ACTHAR	AC	11/13/2013	5	12/02/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
57	63004871001	H.P. ACTHAR	AC	12/04/2013	5	12/11/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
58	63004871001	H.P. ACTHAR	AC	12/20/2013	5	01/01/2014	\$ 31,583.19	\$ -	Pharmacy 3	MD 03
59	63004871001	H.P. ACTHAR	AC	01/06/2014	5	03/05/2014	\$ 25,339.77	\$ 6,243.42	Pharmacy 3	MD 03
60	63004871001	H.P. ACTHAR	AC	01/22/2014	5	03/05/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
61	63004871001	H.P. ACTHAR	AC	02/05/2014	5	03/05/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
62	63004871001	H.P. ACTHAR	AC	02/24/2014	5	03/05/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
63	63004871001	H.P. ACTHAR	AC	03/13/2014	5	03/19/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
64	63004871001	H.P. ACTHAR	AC	04/02/2014	5	04/17/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
65	63004871001	H.P. ACTHAR	AC	04/21/2014	5	04/30/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
66	63004871001	H.P. ACTHAR	AC	05/05/2014	5	05/15/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
67	63004871001	H.P. ACTHAR	AC	05/21/2014	5	05/28/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
68	63004871001	H.P. ACTHAR	AC	06/09/2014	5	06/26/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
69	63004871001	H.P. ACTHAR	AC	06/30/2014	5	07/23/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
70	63004871001	H.P. ACTHAR	AC	07/17/2014	5	07/25/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
71	63004871001	H.P. ACTHAR	AC	08/04/2014	5	08/25/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
72	63004871001	H.P. ACTHAR	AC	08/18/2014	5	09/03/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
73	63004871001	H.P. ACTHAR	AC	09/08/2014	5	09/18/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
74	63004871001	H.P. ACTHAR	AC	09/29/2014	5	10/16/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
75	63004871001	H.P. ACTHAR	AC	10/14/2014	5	10/29/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
76	63004871001	H.P. ACTHAR	AC	10/29/2014	5	11/12/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
77	63004871001	H.P. ACTHAR	AC	11/17/2014	5	11/26/2014	\$ 33,162.34	\$ -	Pharmacy 3	MD 03
78	63004871001	H.P. ACTHAR	AC	12/03/2014	5	12/10/2014	\$ 33,162.34	\$ -	Pharmacy 5	MD 03
79	63004871001	H.P. ACTHAR	AC	12/29/2014	5	01/07/2015	\$ 33,827.13	\$ -	Pharmacy 5	MD 03
Totals					400		\$ 2,538,202.22	\$ 23,969.54		

EXHIBIT 2

Sample False Claim No.	NDC Code	NDC Code Description	Bene Name	Date From Claim	Units Quan Disp	Date Processed	Amt Above OOPT	Amt Below OOPT	Pharm ID	Presc ID
80	63004773101	ACTHAR HP	BA	11/01/2012	5	11/21/2012	\$ 29,403.15	\$ -	Pharmacy 2	MD 15
81	63004871001	H.P. ACTHAR	BB	04/15/2013	5	05/01/2013	\$ 23,897.86	\$ 7,434.98	Pharmacy 3	MD 14
82	63004871001	H.P. ACTHAR	BB	04/29/2013	5	05/15/2013	\$ 31,332.84	\$ -	Pharmacy 3	MD 14
83	63004871001	H.P. ACTHAR	BB	05/21/2013	5	05/29/2013	\$ 31,332.84	\$ -	Pharmacy 3	MD 14
84	63004871001	H.P. ACTHAR	BB	06/07/2013	5	06/12/2013	\$ 31,332.84	\$ -	Pharmacy 3	MD 14
85	63004871001	H.P. ACTHAR	BB	07/01/2013	5	07/27/2013	\$ 31,583.19	\$ -	Pharmacy 3	MD 14
86	63004871001	H.P. ACTHAR	BC	08/29/2013	10	09/12/2013	\$ 55,054.21	\$ 2,776.19	Pharmacy 2	MD 10
87	63004871001	H.P. ACTHAR	BC	10/18/2013	10	10/30/2013	\$ 57,830.40	\$ -	Pharmacy 2	MD 10
88	63004871001	H.P. ACTHAR	BC	12/04/2013	10	12/18/2013	\$ 57,830.40	\$ -	Pharmacy 2	MD 10
89	63004871001	H.P. ACTHAR	BD	05/30/2013	5	06/17/2013	\$ 27,191.80	\$ 3,287.08	Pharmacy 2	MD 11
90	63004871001	H.P. ACTHAR	BE	07/15/2013	5	07/29/2013	\$ 22,893.36	\$ 6,474.84	Pharmacy 3	MD 13
91	63004871001	H.P. ACTHAR	BE	12/05/2013	5	12/09/2013	\$ 29,368.20	\$ -	Pharmacy 3	MD 13
92	63004871001	H.P. ACTHAR	BE	12/10/2013	5	12/16/2013	\$ 29,368.20	\$ -	Pharmacy 3	MD 13
93	63004871001	H.P. ACTHAR	BE	12/16/2013	5	12/23/2013	\$ 29,368.20	\$ -	Pharmacy 3	MD 13
94	63004871001	H.P. ACTHAR	BE	12/27/2013	5	12/30/2013	\$ 29,368.20	\$ -	Pharmacy 3	MD 13
95	63004773101	ACTHAR HP	BF	10/29/2012	10	11/01/2012	\$ 57,485.10	\$ 5,181.18	Pharmacy 4	MD 18
96	63004773101	ACTHAR HP	BF	12/03/2012	10	12/12/2012	\$ 62,666.28	\$ -	Pharmacy 4	MD 18
97	63004871001	H.P. ACTHAR	BF	03/05/2013	10	03/20/2013	\$ 56,735.03	\$ 5,931.25	Pharmacy 4	MD 18
98	63004871001	H.P. ACTHAR	BF	04/08/2013	10	04/17/2013	\$ 62,666.28	\$ -	Pharmacy 4	MD 18
99	63004871001	H.P. ACTHAR	BF	07/15/2013	5	07/30/2013	\$ 31,583.99	\$ -	Pharmacy 4	MD 18
100	63004871001	H.P. ACTHAR	BF	09/24/2013	5	10/03/2013	\$ 31,583.99	\$ -	Pharmacy 4	MD 18
101	63004871001	H.P. ACTHAR	BF	10/22/2013	5	12/02/2013	\$ 31,583.29	\$ -	Pharmacy 4	MD 18
102	63004871001	H.P. ACTHAR	BF	12/23/2013	5	01/08/2014	\$ 31,583.19	\$ -	Pharmacy 4	MD 18
103	63004773101	ACTHAR HP	BG	09/25/2012	10	10/04/2012	\$ 53,041.52	\$ 6,124.61	Pharmacy 4	MD 18
104	63004773101	H.P. ACTHAR	BH	12/11/2013	5	01/01/2014	\$ 24,910.00	\$ 6,673.19	Pharmacy 3	MD 17
105	63004773101	ACTHAR HP	BI	08/03/2011	5	08/12/2011	\$ 26,294.41	\$ -	Pharmacy 6	MD 21
106	63004773101	ACTHAR HP	BI	09/05/2011	5	09/12/2011	\$ 26,294.41	\$ -	Pharmacy 6	MD 21
107	63004773101	ACTHAR HP	BI	10/07/2011	5	10/18/2011	\$ 26,294.33	\$ -	Pharmacy 6	MD 21
108	63004773101	ACTHAR HP	BI	11/05/2011	5	11/10/2011	\$ 26,294.33	\$ -	Pharmacy 6	MD 21
109	63004773101	ACTHAR HP	BI	12/17/2011	5	12/27/2011	\$ 26,294.33	\$ -	Pharmacy 6	MD 21
110	63004773101	ACTHAR HP	BI	05/03/2012	5	05/17/2012	\$ 28,003.00	\$ -	Pharmacy 6	MD 12
111	63004871001	H.P. ACTHAR	BI	11/08/2013	5	11/11/2013	\$ 30,001.12	\$ -	Pharmacy 7	MD 19
112	63004773101	ACTHAR HP	BJ	11/28/2012	10	12/21/2012	\$ 62,571.34	\$ -	Pharmacy 4	MD 18
113	63004773101	ACTHAR HP	BK	02/27/2012	5	03/05/2012	\$ 28,003.00	\$ -	Pharmacy 2	MD 23
114	63004871001	H.P. ACTHAR	BL	09/12/2013	5	10/14/2013	\$ 30,724.15	\$ -	Pharmacy 2	MD 16
115	63004871001	H.P. ACTHAR	BL	09/26/2013	5	10/19/2013	\$ 30,724.15	\$ -	Pharmacy 2	MD 16
116	63004871001	H.P. ACTHAR	BL	10/18/2013	5	11/12/2013	\$ 30,724.15	\$ -	Pharmacy 2	MD 16
117	63004871001	H.P. ACTHAR	BL	11/12/2013	5	12/02/2013	\$ 30,724.15	\$ -	Pharmacy 2	MD 16
118	63004871001	H.P. ACTHAR	BL	03/11/2014	5	03/24/2014	\$ 28,643.67	\$ 3,616.35	Pharmacy 2	MD 16
119	63004871001	H.P. ACTHAR	BM	11/05/2013	5	11/21/2013	\$ 25,418.26	\$ 5,454.74	Pharmacy 2	MD 20
120	63004871001	H.P. ACTHAR	BM	12/04/2013	5	12/23/2013	\$ 30,873.00	\$ -	Pharmacy 2	MD 20
121	63004773101	ACTHAR HP	BN	08/20/2012	5	08/30/2012	\$ 28,761.00	\$ -	Pharmacy 2	MD 22
Totals							\$ 1,477,637.16	\$ 52,954.41		

EXHIBIT 3

Subsidy Date	Fund	Acthar Copay Subsidy Amount Paid for Claim	Corresponding Sample False Claim No.
08/09/2012	MS Acute Exacerbation	\$ 1,564.36	1
10/03/2012	MS Acute Exacerbation	\$ 1,564.36	2
10/19/2012	MS Acute Exacerbation	\$ 1,564.36	3
11/13/2012	MS Acute Exacerbation	\$ 1,564.36	4
11/23/2012	MS Acute Exacerbation	\$ 1,564.36	5
12/28/2012	MS Acute Exacerbation	\$ 1,564.36	6
01/30/2013	MS Acute Exacerbation	\$ 2,417.71	7
02/26/2013	MS Acute Exacerbation	\$ 1,564.36	8
03/22/2013	MS Acute Exacerbation	\$ 1,564.36	9
04/26/2013	MS Acute Exacerbation	\$ 1,564.36	10
05/14/2013	MS Acute Exacerbation	\$ 1,564.36	11
06/14/2013	MS Acute Exacerbation	\$ 1,576.86	12
06/28/2013	MS Acute Exacerbation	\$ 3,153.64	13
07/29/2013	MS Acute Exacerbation	\$ 1,576.86	14
08/12/2013	MS Acute Exacerbation	\$ 1,558.79	15
09/04/2013	MS Acute Exacerbation	\$ 1,558.79	16
09/23/2013	MS Acute Exacerbation	\$ 1,558.79	17
10/21/2013	MS Acute Exacerbation	\$ 1,558.79	18
10/29/2013	MS Acute Exacerbation	\$ 1,558.79	19
11/04/2013	MS Acute Exacerbation	\$ 1,558.79	20
11/12/2013	MS Acute Exacerbation	\$ 1,558.79	21
12/02/2013	MS Acute Exacerbation	\$ 1,558.79	22
09/12/2013	Lupus Exacerbation	\$ 3,445.34	23
09/30/2013	Lupus Exacerbation	\$ 1,543.65	24
10/17/2013	Lupus Exacerbation	\$ 1,543.65	25
11/11/2013	Lupus Exacerbation	\$ 1,543.65	26
11/25/2013	Lupus Exacerbation	\$ 1,543.65	27
12/10/2013	Lupus Exacerbation	\$ 1,543.65	28
12/30/2013	Lupus Exacerbation	\$ 1,543.65	29
01/16/2014	Lupus Exacerbation	\$ 3,401.31	30
02/04/2014	Lupus Exacerbation	\$ 1,620.83	31
02/25/2014	Lupus Exacerbation	\$ 1,620.83	32
03/18/2014	Lupus Exacerbation	\$ 1,620.83	33
04/03/2014	Lupus Exacerbation	\$ 1,620.83	34
04/23/2014	Lupus Exacerbation	\$ 1,620.83	35
05/06/2014	Lupus Exacerbation	\$ 1,620.83	36
05/20/2014	Lupus Exacerbation	\$ 1,620.83	37
06/04/2014	Lupus Exacerbation	\$ 1,620.83	38
06/26/2014	Lupus Exacerbation	\$ 1,620.83	39
07/16/2014	Lupus Exacerbation	\$ 1,620.83	40
07/31/2014	Lupus Exacerbation	\$ 1,620.83	41
08/18/2014	Lupus Exacerbation	\$ 1,620.83	42
09/04/2014	Lupus Exacerbation	\$ 1,620.83	43
09/25/2014	Lupus Exacerbation	\$ 1,620.83	44
10/20/2014	Lupus Exacerbation	\$ 1,620.83	45
11/13/2014	Lupus Exacerbation	\$ 1,620.83	46
12/04/2014	Lupus Exacerbation	\$ 1,620.83	47
12/22/2014	Lupus Exacerbation	\$ 1,653.33	48
07/01/2013	RA Exacerbation	\$ 3,175.92	49
07/17/2013	RA Exacerbation	\$ 1,579.16	50
08/20/2013	RA Exacerbation	\$ 1,579.16	51
09/04/2013	RA Exacerbation	\$ 1,579.16	52
09/24/2013	RA Exacerbation	\$ 1,579.16	53
10/10/2013	RA Exacerbation	\$ 1,579.16	54
10/28/2013	RA Exacerbation	\$ 1,579.16	55

EXHIBIT 4

Subsidy Date	Fund	Acthar Copay Subsidy Amount Paid For Claim	Corresponding Sample False Claim No.
11/01/2012	MS Acute Exacerbation	\$ 1,470.16	80
04/15/2013	RA Exacerbation	\$ 3,557.71	81
04/29/2013	RA Exacerbation	\$ 1,566.64	82
05/21/2013	RA Exacerbation	\$ 1,566.64	83
06/07/2013	RA Exacerbation	\$ 1,566.01	84
07/01/2013	RA Exacerbation	\$ 1,579.16	85
08/29/2013	MS Acute Exacerbation	\$ 4,071.39	86
10/18/2013	MS Acute Exacerbation	\$ 2,891.52	87
12/04/2013	MS Acute Exacerbation	\$ 2,891.52	88
05/30/2013	RA Exacerbation	\$ 2,920.96	89
07/15/2013	MS Acute Exacerbation	\$ 3,359.85	90
12/05/2013	MS Acute Exacerbation	\$ 1,468.41	91
12/10/2013	MS Acute Exacerbation	\$ 1,468.41	92
12/16/2013	MS Acute Exacerbation	\$ 1,468.41	93
12/27/2013	MS Acute Exacerbation	\$ 1,468.41	94
10/25/2012	RA Exacerbation	\$ 5,186.54	95
12/03/2012	RA Exacerbation	\$ 3,113.31	96
03/05/2013	RA Exacerbation	\$ 5,569.33	97
04/08/2013	RA Exacerbation	\$ 3,113.31	98
07/15/2013	RA Exacerbation	\$ 1,559.20	99
09/24/2013	RA Exacerbation	\$ 1,559.20	100
10/22/2013	RA Exacerbation	\$ 1,559.16	101
12/23/2013	RA Exacerbation	\$ 1,559.16	102
09/25/2012	RA Exacerbation	\$ 5,289.25	103
12/11/2013	MS Acute Exacerbation	\$ 3,464.47	104
08/03/2011	MS Acute Exacerbation	\$ 1,304.72	105
09/05/2011	MS Acute Exacerbation	\$ 1,304.72	106
10/07/2011	MS Acute Exacerbation	\$ 1,304.72	107
11/05/2011	MS Acute Exacerbation	\$ 1,304.72	108
12/17/2011	MS Acute Exacerbation	\$ 1,304.72	109
05/03/2012	MS Acute Exacerbation	\$ 1,400.15	110
11/08/2013	MS Acute Exacerbation	\$ 1,500.06	111
11/28/2012	RA Exacerbation	\$ 3,128.57	112
02/27/2012	MS Acute Exacerbation	\$ 1,400.15	113
09/12/2013	RA Exacerbation	\$ 1,536.20	114
09/26/2013	RA Exacerbation	\$ 1,536.20	115
10/18/2013	RA Exacerbation	\$ 1,536.20	116
11/12/2013	RA Exacerbation	\$ 1,536.20	117
03/11/2014	RA Exacerbation	\$ 3,142.71	118
11/05/2013	RA Exacerbation	\$ 3,607.87	119
12/04/2013	RA Exacerbation	\$ 1,543.65	120
08/20/2012	MS Acute Exacerbation	\$ 1,438.05	121
Totals		\$ 95,117.74	

HCSC v. Mallinkrodt ARD LLC, Case No. RG20056354

Exhibit 3 to Declaration of Matthew S. Weiler



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THE UNITED STATES
DEPARTMENT OF JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, June 5, 2019

United States Intervenes In False Claims Act Lawsuit Against Drug Maker Mallinckrodt Alleging Illegal Kickbacks

The United States filed a complaint under the False Claims Act against Mallinckrodt ARD LLC, formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc., in the U.S. District Court for the Eastern District of Pennsylvania, the Department of Justice announced today. The government alleges that Mallinckrodt and Questcor (collectively Mallinckrodt) engaged in conduct that violated the False Claims Act by using a foundation as a conduit to pay kickbacks in connection with its drug H.P. Acthar Gel (Acthar) from 2010 through 2014.

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, which may take the form of a copayment, coinsurance, or a deductible (collectively “copays”). Congress included copay requirements in the Medicare program, in part, to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration—which includes money or any other thing of value—to induce Medicare patients to purchase the company’s drugs. This prohibition extends to the payment of patients’ copay obligations.

The government alleges that Mallinckrodt used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as “free” to doctors and patients while increasing its price. Mallinckrodt allegedly paid these illegal subsidies through three funds that Mallinckrodt had a foundation set up to pay Acthar Medicare copays to the exclusion of other drugs. The government alleges that Mallinckrodt then routed patients with Acthar prescriptions to these funds. Mallinckrodt allegedly made continuing payments as the sole “donor” to these funds, to keep subsidizing Acthar Medicare copays as it expanded its sales of the drug. The government alleges that the Company paid these subsidies to induce Medicare-reimbursed purchases of Acthar at its ever-increasing price, and used the subsidies to counteract doctor and patient concerns about the drug’s high cost and to market the drug as “free.” The government further alleges that since its acquisition of Acthar in 2001, Mallinckrodt had raised its price from approximately \$50 to over \$32,200 per 5 milliliter vial by the end of 2014.

“Illegal inducements increase the costs paid by the American taxpayer and distort the market forces that otherwise could control those costs,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division. “This lawsuit and prior enforcement actions make clear that the Department will hold accountable drug companies that pay illegal kickbacks to facilitate increased drug prices.”

“Medicare Part D is an important program that our nation instituted to help seniors cover prescription drug costs, and Congress enacted safeguards to ensure Part D’s fiscal viability for those citizens,” said United States Attorney William M. McSwain. “In my office’s continued commitment to fighting health care fraud, we will not allow drug companies to use so-called charitable patient assistance funds to do what they otherwise cannot do – pay patients’ co-pays to circumvent these safeguards and increase their profits.”

"Medicare rules are designed to protect beneficiaries and taxpayer dollars," said Maureen R. Dixon, Special Agent in Charge of the Philadelphia Regional Office of the Inspector General, Department of Health and Human Services. "HHS-OIG and the U.S. Attorney's Office will continue to work together to fight health care fraud and investigate allegations of co-pay and kickback violations."

The allegations that are the subject of the government's complaint were originally brought in two cases filed under the whistleblower, or qui tam, provision of the False Claims Act. The act permits private parties to sue for fraud on behalf of the United States and to share in any recovery. The act also permits the government to intervene in such actions, as the government previously did in the two whistleblower cases here, which are captioned *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, No. 12-CV-0175 (E.D. Pa.), and *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.*, No. 13-CV-1776 (E.D. Pa.). The government's pursuit of these matters illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement can be reported to the Department of Health and Human Services, at 800-HHS-TIPS (800-447-8477).

This matter is being handled by the Civil Division's Commercial Litigation Branch, and the U.S. Attorney's Office for the Eastern District of Pennsylvania, with assistance from the U.S. Department of Health and Human Services Office of Inspector General.

The claims asserted by the United States are allegations only and there has been no determination of liability.

Topic(s):

False Claims Act

Component(s):

Civil Division

USAO - Pennsylvania, Eastern

Press Release Number:

19-620

Updated June 5, 2019

HCSC v. Mallinkrodt ARD LLC, Case No. RG20056354

Exhibit 4 to Declaration of Matthew S. Weiler

CHAPTER 178

(HB 323)

AN ACT relating to crimes affecting insurance.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 304.47-020 is amended to read as follows:

- (1) For the purposes of this subtitle, a person or entity commits a "fraudulent insurance act" if he or she engages in any of the following, including but not limited to matters relating to workers' compensation:
- (a) Knowingly and with intent to defraud or deceive presents, causes to be presented, or prepares with knowledge or belief that it will be presented to an insurer, Kentucky Claims Commission, Special Fund, or any agent thereof:~~[(b)]~~
 - 1. Any written or oral statement as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or from a "self-insurer" as defined by KRS Chapter 342, knowing that the statement contains any false, incomplete, or misleading information concerning any fact or thing material to a claim; **or**
 - ~~[(b)] Knowingly and with intent to defraud or deceive presents, causes to be presented, or prepares with knowledge or belief that it will be presented to an insurer, Kentucky Claims Commission, or any agent thereof;~~
 - 2. Any statement as part of, or in support of, an application for an insurance policy, for renewal, reinstatement, or replacement of insurance, or in support of an application to a lender for money to pay a premium, knowing that the statement contains any false, incomplete, or misleading information concerning any fact or thing material to the application;
 - ~~(b) [(c)]~~ Knowingly and willfully transacts any contract, agreement, or instrument which violates this title;
 - ~~(c) [(d)]~~ Knowingly and with intent to defraud or deceive:~~[(e)]~~
 - 1. Receives money for the purpose of purchasing insurance, and fails to obtain insurance;
 - ~~[(e)] Knowingly and with intent to defraud or deceive;~~
 - 2. Fails to make payment or disposition of money or voucher as defined in KRS 304.17A-750, as required by agreement or legal obligation, that comes into his or her possession while acting as a licensee under this chapter;
 - 3. *Presents, causes to be presented, or prepares with knowledge or belief that it will be presented to or by an insurer, or to the commissioner, any statement, knowing that the statement contains any false, incomplete, or misleading information concerning any material fact or thing, as part of, or in support of one (1) or more of the following:*
 - a. *The rating of an insurance policy;*
 - b. *The financial condition of an insurer;*
 - c. *The formation, acquisition, merger, reconsolidation, dissolution, or withdrawal from one (1) or more lines of insurance in all or part of this Commonwealth by an insurer; or*
 - d. *A document filed with the commissioner; or*
 - 4. *Engages in any of the following:*
 - a. *Solicitation or acceptance of new or renewal insurance risks on behalf of an insolvent insurer; or*
 - b. *Removal, concealment, alteration, tampering, or destruction of money, records, or any other property or assets of an insurer;*
 - ~~(d) [(f)]~~ Issues or knowingly presents fake or counterfeit insurance policies, certificates of insurance, insurance identification cards, insurance binders, or any other documents that purport to evidence insurance;

ACTS OF THE GENERAL ASSEMBLY

~~(e)(g)~~ Makes any false or fraudulent representation as to the death or disability of a policy or certificate holder in any written statement or certificate for the purpose of fraudulently obtaining money or benefit from an insurer;

~~(f)(h)~~ Engages in unauthorized insurance, as *set forth*~~[defined]~~ in KRS 304.11-030;

~~(i)~~ Knowingly and with intent to defraud or deceive, presents, causes to be presented, or prepares with knowledge or belief that it will be presented to or by an insurer, or to the commissioner, any statement, knowing that the statement contains any false, incomplete, or misleading information concerning any material fact or thing, as part of, or in support of one (1) or more of the following:

- ~~1. The rating of an insurance policy;~~
- ~~2. The financial condition of an insurer;~~
- ~~3. The formation, acquisition, merger, reconsolidation, dissolution, or withdrawal from one (1) or more lines of insurance in all or part of this Commonwealth by an insurer; or~~
- ~~4. A document filed with the commissioner;~~

~~(j)~~ Knowingly and with intent to defraud or deceive, engages in any of the following:

- ~~1. Solicitation or acceptance of new or renewal insurance risks on behalf of an insolvent insurer; or~~
- ~~2. Removal, concealment, alteration, tampering, or destruction of money, records, or any other property or assets of an insurer;}~~ or

~~(g)(k)~~ Assists, abets, solicits, or conspires with another to commit a fraudulent insurance act in violation of this subtitle.

(2) (a) Except as provided in paragraphs (b) and (c) of this subsection, a person convicted of a violation of subsection (1) of this section shall be guilty of a misdemeanor where the aggregate of the claim, benefit, or money referred to in subsection (1) of this section is less than or equal to five hundred dollars (\$500), and shall be punished by:

1. Imprisonment for not more than one (1) year;
2. a fine, per occurrence, of not more than one thousand dollars (\$1,000) per individual nor five thousand dollars (\$5,000) per corporation or twice the amount of gain received as a result of the violation, whichever is greater; or
3. Both imprisonment and a fine as set forth in subparagraphs 1. and 2. of this paragraph.

(b) Except as provided in paragraph (c) of this subsection, where the claim, benefit, or money referred to in subsection (1) of this section exceeds an aggregate of five hundred dollars (\$500), a person convicted of a violation of subsection (1) of this section shall be guilty of a felony and shall be punished by:

1. Imprisonment for not less than one (1) nor more than five (5) years;
2. A fine, per occurrence, of not more than ten thousand dollars (\$10,000) per individual nor one hundred thousand dollars (\$100,000) per corporation or twice the amount of gain received as a result of the violation, whichever is greater; or
3. Both imprisonment and a fine as set forth in subparagraphs 1. and 2. of this paragraph.

(c) Any person, with the purpose to establish or maintain a criminal syndicate, or to facilitate any of its activities, as set forth in KRS 506.120(1), shall be guilty of engaging in organized crime, a Class B felony, and shall be punished by:

1. Imprisonment for not less than ten (10) years nor more than twenty (20) years;
2. A fine, per occurrence, of not more than ten thousand dollars (\$10,000) per individual nor one hundred thousand dollars (\$100,000) per corporation, or twice the amount of gain received as a result of the violation; whichever is greater; or
3. Both imprisonment and a fine, as set forth in subparagraphs 1. and 2. of this paragraph.

(d) In addition to imprisonment, the assessment of a fine, or both, a person convicted of a violation of paragraph (a), (b), or (c) of subsection (2) of this section may be ordered to make restitution to any victim who suffered a monetary loss due to any actions by that person which resulted in the adjudication of guilt,

CHAPTER 178

3

and to the division for the cost of any investigation. The amount of restitution shall equal the monetary value of the actual loss or twice the amount of gain received as a result of the violation, whichever is greater.

- (3) Any person damaged as a result of a violation of any provision of this section ~~when there has been a criminal adjudication of guilt~~ shall have a cause of action to recover compensatory damages, plus all reasonable investigation and litigation expenses, including attorneys' fees, at the trial and appellate courts.
- (4) The provisions of this section shall also apply to any agent, unauthorized insurer or its agents or representatives, or surplus lines carrier who, with intent, injures, defrauds, or deceives any claimant with regard to any claim. The claimant shall have the right to recover the damages provided in subsection (3) of this section.

Signed by Governor April 26, 2018.

EXHIBIT 46

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp	No. RG20056354 Minutes
Plaintiff/Petitioner(s)	
VS.	
Mallinckrodt ARD LLC	
Defendant/Respondent(s)	
(Abbreviated Title)	

Department 19 Honorable Stephen Kaus , Judge

Cause called for Case Management Conference on June 23, 2020.

Plaintiff Health Care Service Corp not appearing.
Defendant Mallinckrodt ARD LLC not appearing.
Defendant Mallinckrodt PLC not appearing.

ORDER re: CASE MANAGEMENT

The Court has ordered the following after review of the case, including timely filed Case Management Statements, without a conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 08/05/2020 at 03:00 PM in Dept. 19.

To coincide with demurrer.

NOTICES

The Court orders counsel and/or self-represented parties to obtain a copy of this order from the court's website <http://www.alameda.courts.ca.gov/domainweb>.

Minutes of 06/23/2020
Entered on 06/24/2020

Chad Finke Executive Officer / Clerk of the Superior Court

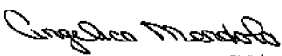
By  Digital
Deputy Clerk

EXHIBIT 47

ENDORSED
FILED
ALAMEDA COUNTY

JUL 21 2020

CLERK OF THE SUPERIOR COURT
Anita Dhu

ECOPY

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**REPLY IN SUPPORT OF THE
DEFENDANT MALLINCKRODT
ENTITIES' DEMURRER AND
MOTION TO STRIKE**

Date: August 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Res. Nos. 2179414 & 2179416

Action Filed: February 27, 2020

BY FAX

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I. INTRODUCTION

In its effort to oppose Mallinckrodt's Demurrer and Motion to Strike ("Demurrer" and "Mot. to Strike"), HCSC makes telling concessions relating to each of the five categories of alleged misconduct that underpin the complaint:

1. **Exclusive Distribution.** HCSC *admits* that "exclusive distribution arrangements are *not* illegal in themselves" (Opp. 9 (emphasis added)), and thus contradicts the complaint's legal conclusions to the contrary (*e.g.*, Cmpl. ¶ 11). Shifting theories in its opposition, HCSC invokes case law involving (i) exclusive *dealing* not exclusive *distribution*, and (ii) a theory of misconduct so implausible that HCSC rightly does not allege here.
2. **Copay Assistance.** HCSC abandons its allegations that, when accepting copay assistance, its members violate commercial bribery statutes (Mem. 21:7–26) or breach any contractual obligation to HCSC (Opp. 17:20–23). And it elides the fact that, by mid-2014, HCSC had *constructive* knowledge of its claims, by offering the non sequitur that HCSC's alleged lack of *actual* knowledge cannot be contradicted on a demurrer.
3. **Off-Label Promotion.** HCSC admits that "the thrust of HCSC's claims is *not* that the off-label promotions themselves were misrepresentations" (*id.* at 12:16 (emphasis in original)); HCSC never heard, let alone relied on, any off-label promotion (*id.* at 13:10–13); and HCSC knows of *no* details or *any* examples of the promotion it attempts to challenge (*id.* at 13:1).
4. **Payments to Doctors.** Denying that its charge of bribery is a mere legal conclusion, HCSC fails to identify a single factual allegation distinguishing the alleged Mallinckrodt payments from lawful compensation for speaking and research. HCSC also admits that it pre-reviewed each Acthar® Gel ("Acthar") prescription for medical necessity while knowing of the allegedly improper payments; HCSC thus cannot explain how the payments caused injury.
5. **Acquisition of Synacthen.** HCSC expressly admits that its theories of harm to competition and injury from Questcor's acquisition are premised on a construct under which Synacthen is a generic version of Acthar (Opp. 6:16–18), which the complaint contradicts (Cmpl. ¶ 15).

These concessions signal the strength of the Demurrer and Motion to Strike, which should be granted. HCSC's assertion that Mallinckrodt's arguments "have been rejected by other courts that have sustained substantially identical claims" (Opp. 1:14–26) relies on selective and inaccurate descriptions of their decisions, which Mallinckrodt overviewed comprehensively in its opening brief (Mem. 11:6–8 & n.1). And HCSC's resort to the standard of review understates both the applicable level of scrutiny and the Court's power to strike irrelevant matter from the complaint. In that regard, Mallinckrodt's request for relief follows the First Appellate District's guidance precisely.

II. THE STANDARD OF REVIEW

The standard of review poses no obstacle to Mallinckrodt's requested relief. HCSC argues that the Court must accept as true all of the complaint's conclusory allegations "however improbable they may be," quoting *Del E. Webb Corp. v Structured Materials Co.*, 123 Cal. App. 3d 593, 604

(1981). Opp. 4:19-21. But *Del E. Webb* rejected allegations contradicted by judicially noticeable facts because “courts . . . will not close their eyes . . . to facts which are judicially noticed;” in the passage HCSC relies on, the court merely accepted *factual* allegations contradicted by *testimony* because a demurrer does not entail “a contested evidentiary hearing.” 123 Cal. App. 3d at 604–05. Moreover, HCSC ignores authorities holding that, outside the context of the common counts, legal conclusions can be disregarded; antitrust claims, fraud-based claims, and attenuated causation theories are subject to heightened pleading requirements; and allegations of fact on which liability depends “must be plausible.” Mem. 17:2–10, 27:16–22, 29:15–19, 32:5–8 (citing cases); *see also* Weil & Brown, Cal. Practice Guide: Civil Proc. Before Trial ¶¶ 7:43, 7:44.2, 7:46 (2020).

HCSC also argues that the Court cannot strike clear overreach from the complaint because there is no “procedural ‘line item veto’ for the civil defendant,” quoting *PH II, Inc. v. Superior Court*, 33 Cal. App. 4th 1680, 1683 (1995). Opp. 24:6–25:17 & n.17. But Mallinckrodt followed *PH II*’s clear guidelines for use of a motion to strike where “a portion of a cause of action [is] substantively defective.”¹ *See* Demurrer at 4–8; Mot. to Strike at 2–4. HCSC’s authorities (Opp. 24:6–20) involved a demurrer that should have been a motion to strike or a motion to strike allegations bearing on intent behind actionable conduct. To the extent the latter appears applicable here, allegations as to the conduct’s actionable nature should still be stricken.

III. ARGUMENT

A. The Distribution Model For Acthar Is Presumptively Lawful and HCSC Fails to Plead Otherwise.

Mallinckrodt has demonstrated that its exclusive distribution agreement with CuraScript was presumptively lawful under the laws of California and 40 other states and that HCSC’s allegations of any supposed anticompetitive effects defy economic and legal sense. Mem. 17:20–20:16; RJN Ex. L. HCSC responds by admitting (as it must) that “exclusive distribution agreements are not illegal in themselves.” Opp. 9:18–19. Unsurprisingly, HCSC’s argument offered to overcome this admission fails in all respects.

¹ 33 Cal. App. 4th at 1682-83 (“Although a defendant may not demur to that portion, in such cases, the defendant should not have to suffer discovery and navigate the often dense thicket of proceedings in summary adjudication.” Rather, a motion to strike can “attack [that] portion of the cause of action” that “violat[es] . . . the applicable statute of limitations,” “fail[s] to state facts showing a . . . wrong committed by the defendant,” or requests an improper remedy.).

1 Quoting *United States v. Dentsply International, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005),
 2 HCSC argues that “exclusive distribution arrangements . . . can run afoul of the antitrust laws as ‘an
 3 improper means of maintaining a monopoly.’” Opp. 9:18–21. *Dentsply* involved a different type
 4 of exclusive arrangement, however. Dentsply, the dominant provider of artificial teeth, coerced its
 5 dealers to “offer Dentsply teeth either as the only or dominant choice.” 399 F.3d 181 at 185, 192.
 6 The case thus involved exclusive *dealing*, which can harm competition when a monopolist uses it
 7 so extensively as to foreclose competitors from needed distribution. Here, in contrast, HCSC does
 8 not allege any restrictions on CuraScript’s ability to distribute any pharmaceuticals of its choosing.

9 HCSC also invokes oft-quoted language from *Continental Ore Co. v. Union Carbide &*
 10 *Carbon Corp.*, 370 U.S. 690 (1962), to proclaim that “in the antitrust context, the character and
 11 effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but by
 12 looking at it as a whole.” Opp. 9 (internal quotations omitted). While all acts that may be
 13 anticompetitive should be considered “as a whole,” no “synergistic result” can arise from “acts
 14 constitut[ing] reasonable, pro-competitive conduct for a monopolist.” *Cal. Computer Prods., Inc.*
 15 *v. IBM*, 613 F.2d 727, 746 (9th Cir. 1979). The exclusive distribution agreement has no
 16 anticompetitive effect; so it adds nothing to any other alleged scheme’s anticompetitive effect.

17 HCSC concludes with a barrage of antitrust buzz words applying the inapplicable standard
 18 for exclusive *dealing* (Opp. 10:5–11:1) and numerous cites to *City of Rockford v. Mallinckrodt ARD,*
 19 *Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019), which allowed an antitrust challenge to Mallinckrodt’s
 20 exclusive distributorship to proceed past the pleadings. The reasoning in *Rockford*, however, is
 21 where HCSC got its flawed view of the potential anticompetitive effects of an exclusive distribution
 22 agreement, and the *Rockford* court was impermissibly assessing the lawful distributorship in
 23 connection with other parts of an alleged scheme. 360 F. Supp. 3d at 744–45. That scheme is *not*
 24 one HCSC alleges, because it is facially implausible—allegations that CuraScript agreed to, rather
 25 than acquiesced in, price increases for Acthar, *see Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S.
 26 752, 764 n.9 (1984) (holding that “acquiescence” is not enough establish a meeting of the minds).
 27 In sum, HCSC’s allegations relating to the distribution of Acthar do not state a claim.
 28

B. HCSC's Allegations Regarding Co-Pay Assistance Do Not State a Claim.

HCSC implicitly admits that copay assistance is not a violation of state commercial bribery statutes, and thus not a predicate act supporting its RICO claims. Its oppositions to the other two reasons to eliminate copay assistance from the case lack merit.

1. HCSC's Claims Based on the Allegation that CDF Co-Pay Assistance Funds Violated the Federal Anti-Kickback Statute Are Time Barred.

Without dispute, HCSC's claims based on the Acthar-only nature of certain CDF copay assistance funds are barred, whether by a five-year limitation period or other legal defenses, *if HCSC was on constructive notice of those claims by mid-2014*. Mem. 22:3–10 & n.6; RJN Ex. M (listing limitations periods or other defenses); Opp. RJN at 8:10-18 (not contesting authorities in RJN Ex. M). As a matter of law, HCSC had such notice because OIG's May 2014 SAB created grounds for suspicion that would have been confirmed by a quick Internet search and 2013 *New York Times* reporting that certain CDF copay assistance funds were defined in a way that "applies only to Acthar." Mem. 23:1–16; RJN Ex. D at 30. This showing forces HCSC into convoluted positions.

First, HCSC argues that "judicially noticeable documents [like the *New York Times* article] . . . cannot be used on demurrer to resolve *factual* disputes" and pretends that the dispute concerns HCSC's allegation that it lacked *actual* knowledge until 2019. Opp. 19:22–27 (emphasis added), 20:18–23. At this stage, Mallinckrodt contests not *that* (implausible) factual allegation, but the *legal conclusion* that HCSC lacked constructive notice. Mem. 23:1–18. HCSC's authorities (Opp. 19:25–27, 20:19–22) thus address a point not in dispute. And, as recognized in *McKelvey v. Boeing North America, Inc.*, news reporting can "show that, at a time outside the statute of limitations, plaintiffs had notice of or information of circumstances sufficient to put a reasonable person on inquiry," and "[t]he accuracy of the reporting is irrelevant." 74 Cal. App. 4th 151, 162 (1999) (approving of judicial notice of article to support demurrer based on constructive notice), *abrogated on other grounds* (contra (Opp. 22 n.13)) *as recognized by*, 5 Cal. 5th 627, 633 n.3 (2018).

Second, HCSC disputes that it saw the news articles, of which there were two. Opp. at 21:17–26; Opp. RJN at 2:13–20. Here again HCSC misconstrues the point. HCSC, as a sponsor of Medicare plans (Cmplt ¶ 18), had an interest in the OIG's May 2014 SAB, which was published in the Federal Register, and is therefore charged with knowledge of its contents. 44 U.S.C. § 1507.

1 The 2014 SAB thus put HCSC on notice of the emergence of “narrowly defined disease funds”
 2 covering copays for “expensive or specialty drugs” for Medicare patients and the funds’ exposure
 3 to Anti-Kickback Act scrutiny. 79 Fed. Reg. 31,120, 31,121–22 (May 30, 2014). A reasonable
 4 third-party payer would conduct some investigation into any copay assistance program like that
 5 described in the 2014 SAB for expensive drugs it covers. According to the complaint, Acthar was
 6 one of *the* most expensive drugs HCSC covered in 2013 (Cmplt. ¶¶ 3, 8, 85, 215). As a reasonable
 7 payer, HCSC would have conducted some investigation into the copay assistance program for
 8 Acthar and readily uncovered the *New York Times* and *Barron’s* articles. HCSC’s causes of action
 9 accrued, and any tolling ends at that point as a matter of law, when “by the exercise of reasonable
 10 diligence, [HCSC] should have discovered” its claims. *Bernson v. Browning-Ferris Indus.*, 7 Cal.
 11 4th 926, 931 (1994); *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 807–08 (2005).² That time
 12 was outside the limitations period applicable here, and HCSC’s claims are time barred.

13 *Finally*, HCSC argues that the *Humana* court rejected the argument that publicly available
 14 information put payers on notice of the Acthar-only nature of certain CDF funds. Opp. 20:23–
 15 21:10. But that decision turned on the absence of “anything in the [first amended complaint] . . . to
 16 support the fact that it was publicized . . . that the funds only covered Acthar.” *Humana Inc. v.*
 17 *Mallinckrodt ARD LLC*, 2020 WL 3041309, at *11 (C.D. Cal. Mar. 9, 2020). The articles are on
 18 the record for a motion to dismiss Humana’s second amended complaint as they are here.

19 **2. Co-Pay Assistance Is Not a Tortious Interference with Contracts.**

20 The Court should give short shrift to HCSC’s tortious interference claim. Contrary to the
 21 legal conclusions in the complaint (Cmplt. ¶¶ 286–88), HCSC now implicitly admits its contracts
 22 *do not* prevent members from accepting assistance to meet their co-pay obligations (Opp. 17:20–
 23 18:2). Quoting *PG&E v. Bear Stearns & Co.*, 50 Cal. 3d 1118 (1990), HCSC falls back to a position
 24 that manufacturer-sponsored co-pay assistance is a “disruption of the contractual relationship.”
 25 Opp. 17:21–24. But there, the “defendant induced a party to a contract to seek a judicial

26 ² HCSC’s effort to distinguish these cases because “HCSC’s allegations control” (Opp. 22 n.13)
 27 ignores the cases’ holdings on inquiry notice and constructive knowledge. HCSC’s authorities
 28 (Opp. 21:19-26) are distinguishable because the plaintiffs in those cases were *not* on inquiry notice
 and thus had no reason to search out news reports. Similarly, HCSC’s reliance on fraudulent
 concealment (Opp. 22:3–13 & nn.13 & 14) is misplaced because related tolling ends upon inquiry
 notice of misconduct. *Bernson*, 7 Cal. 4th at 931.

determination whether it may terminate the contract according to its terms.” 50 Cal. 3d at 1123. HCSC does not allege any such disruption, and *PG&E* is inapposite. HCSC’s remaining arguments (Opp. 18:3–10) relate to the point conceded (*i.e.*, no breach) and misconstrue Mallinckrodt’s authorities.

C. HCSC Lacks Support to Conclude That Doctor Payments Were Unlawful.

In defense of its allegations of bribery, HCSC points to the very legal conclusions that Mallinckrodt has shown insufficiently distinguish *lawful* payments from bribes. *Compare* Mem. 25:4–26:2, *with* Opp. 15:15–21. In an effort to muster facts plausibly supporting the charge, which is the standard under California procedure on these claims (Mem. 17:5–10):

- HCSC attempts to walk back its admission that Mallinckrodt’s payments to doctors were within industry standard (Opp. 16, n.9), but provides no facts to indicate that any particular payment was excessive in relation to services rendered, *see Galiano v. Fid. Nat’l Title Ins. Co.*, 684 F.3d 309, 315 (2d Cir. 2012) (dismissing claims for illegal kickbacks where alleged “substantial differences” between the prices and costs of services were “mere conjecture”);
- HCSC argues that Mallinckrodt is impermissibly contesting the truth or accuracy of the 2018 JAMA Network study on which HCSC relies (Opp. 16:4–14), even though the study’s authors themselves disclaimed that the study cannot be used to support the inference HCSC urges. Mem. 25:26–26:2 (quoting RJN Ex. I at 84); and
- HCSC resorts to citing Mallinckrodt’s settlement with DOJ over the allegation that meals and entertainment provided by 12 sales representatives between 2009–2013 were excessive in amount (Opp. 17:8–18), but allegations of that settlement should be stricken (Mem. 25:13–19) and do not, standing alone, support HCSC’s effort to project those allegations through the entire proposed nine-year damages period.³

In defense of its allegations on causation, HCSC similarly points to conclusory assertions (Opp. 16:15–16), and it disputes neither that HCSC was aware of the payments to prescribing doctors during the pre-authorization process (*id.* at 17, n.10) nor that the prescriptions written were medically appropriate (*id.* at 16:15–17:7). HCSC thus completely ignores cases in which courts have dismissed analogous claims by third-party payers who did not allege any instances where physicians had prescribed drugs on the basis of a manufacturer’s alleged misconduct rather than the physicians’ own judgment of what was in their patients’ best interests. Mem. 26:21–27:6 (citing cases). And HCSC’s authorities (Opp. 16:17–17:7) are distinguishable.⁴

³ HCSC relies on *In re Nat’l Assoc. of Music Merchants, Musical Instruments & Equip. Antitrust Litig.* (Opp. 17:11–14), but the court dismissed claims of wrongdoing *while considering* a related FTC investigation and consent decree. 2011 WL 3702453, at *1–2 (S.D. Cal. Aug. 22, 2011).

⁴ *State ex rel. Wilson v. Superior Court*, 227 Cal. App. 4th 579, 587 (2014) (scheme that involved “shaking the doctors down”); *Blue Cross of Cal. Inc. v. Insys Therapeutics Inc.*, 390 F. Supp. 3d 996, 1002, 1008 (D. Ariz. 2019) (false representations that “the patient had a cancer diagnosis and

D. HCSC’s Allegations of Off-Label Promotion Lack the Particularity Necessary to Plead Fraud or Causation.

HCSC admits that “the thrust of HCSC’s claims is *not* that the off-label promotions themselves were misrepresentations.” Opp. 12:16 (emphasis in original). That admission is fatal. HCSC disagrees because it relies on “statements of compliance with the law” that it claims were false because of the alleged off-label promotion. *Id.* at 12:17–18. But that argument runs headlong into the sound, First Amendment-inspired holding of *United States v. Caronia* that a pharmaceutical company does *not* engage in unlawful “misbranding” under the FDCA when engaging in “the truthful off-label promotion of FDA-approved prescription drugs.” 703 F.3d 149, 168 (2d Cir. 2012). HCSC’s effort to limit *Caronia*’s reach to criminal prosecutions for off-label promotion (Opp. 12, n.6) ignores its holding that the FDCA does not “prohibit” truthful off-label promotion, 703 F.3d at 168, and HCSC’s own theory that the *unlawful* nature of the conduct is the basis for its claims. *Arvizu v. Medtronic Inc.* provides no support to HCSC because that case involved “allegations of misrepresentation in off-label promotion.” 41 F. Supp. 3d 783, 794 (D. Ariz. 2014).

Equally dispositive is HCSC’s failure to plead any specific instances of off-label promotion. Mem. 27:15–28:2. Courts require a plaintiff to plead off-label promotion with particularity. *E.g.*, *U.S. ex rel. Modglin v. DJO Global Inc.*, 114 F. Supp. 3d 993, 1014–18 (C.D. Cal. 2015). HCSC asks the Court to excuse its failure to do so on the ground that HCSC never heard any such promotion and should thus be subject to the relaxed pleading standard of *Committee On Children’s Television, Inc. v. General Foods Corp.*, 35 Cal. 3d 197 (1983). Opp. 13:1–8. Even under *Children’s Television*, however, plaintiffs are required to provide “a representative selection of advertisements, to state the misrepresentations made by those advertisements, and to indicate the language or images upon which any implied misrepresentations are based.” 35 Cal. 3d at 218. HCSC does not do any such thing, and its off-label claims fail even under a lesser pleading standard.

Finally, the above points underscore that HCSC has failed to plead any injury to HCSC, given that doctors exercised independent judgment to prescribe Acthar for legitimate conditions and HCSC reviewed *every* prescription before paying for it (Mem. 28:19–29:3). Contrary to HCSC’s

was tolerant to opioids” to secure authorization); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 42–43 (D. Mass. 2011) (claims “for the value of the excess product”).

suggestion (Opp. 13:13–14:15), the cases on which HCSC relies did not deny that doctors’ exercise of independent judgment can break the chain of causation. Rather, *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co. Ltd.*, for example, involved concealment of a drug’s risk of causing bladder cancer, which the court held could “materially influence prescribing physicians’ decisions,” and which the court distinguished from instances of off-label promotion related to efficacy at issue in *Sidney Hillman* and *UFCW Local 1776* (cited at Mem. 28:25–29:3). 943 F.3d 1243, 1258 (9th Cir. 2019). No similar facts are alleged by HCSC.

E. HCSC’s Challenge to Questcor’s Acquisition of Synacthen Rights Fails to State a Claim.

1. HCSC Fails to Allege a Relevant Antitrust Market in which Acthar Competes.

HCSC does not dispute that its proposed ACTH-only market excludes medical substitutes for Acthar’s 19 different FDA-approved indications. HCSC instead insists that relevant antitrust markets in pharmaceutical cases should include only “a brand drug and its biological equivalent.” Opp. 6:1–2. HCSC is wrong: “*The tests are constant* [no matter the industry]. Th[e] market is composed of products that have reasonable interchangeability for the purpose for which they are produced—price, use and qualities considered.” *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956) (emphasis added). Like any other market, a pharmaceutical market is defined by reference to *all* economic (including medical) substitutes and the nature of the alleged restraint—factors that warrant including different pharmaceuticals in the same market. *See, e.g., Mylan Pharm. Inc. v. Warner Chilcott plc*, 838 F.3d 421, 436–38 (3d Cir. 2016) (rejecting market limited to brand and generic drug because all “oral tetracyclines” can “treat acne”).

HCSC’s related contention that medical substitutes for Acthar are not part of the relevant market because they are not biological equivalents (Opp. 6:23–24) misapprehends the concept of economic substitutability. HCSC’s cite to *E.I. du Pont* is instructive. There, the Supreme Court affirmed that cellophane was part of a broader market for flexible packing materials despite physical differences and the price of cellophane being two or three times more than competing wrapping materials. 351 U.S. at 396–400. The Court warned that “where there are market alternatives that buyers may readily use for their purposes, illegal monopoly does not exist merely because the

product said to be monopolized differs from others. If it were not so, only physically identical products would be a part of the market.” *Id.* at 394.

None of HCSC’s pharmaceutical cases justifies a market limited to Acthar. While *In re Nexium (Esomeprazole) Antitrust Litigation* found that a “brand-name drug and its generic analogs can fall within the bounds of a relevant market,” the restraint in that case allegedly cut off generic competition. 968 F. Supp. 2d 367, 388 (D. Mass. 2013) (emphasis added); *see also In re Cipro I & II*, 61 Cal. 4th 116, 157 (2015); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319, n.40 (S.D. Fla. 2005); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 623 (E.D. Mich. 2000). And *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, merely found a lack of “other functionally and chemically similar drugs [are] on the market *designed to treat the same symptoms*.” 296 F. Supp. 3d 1142, 1172, n.36 (N.D. Cal. 2017) (emphasis added). Here, HCSC admits that Synacthen is not a generic version of Acthar (Cmpl’t. ¶ 162) and that non-ACTH drugs can be substituted for Acthar to treat particular conditions (Mem. 31:1–12).

HCSC tellingly ignores almost every market definition case cited by Mallinckrodt (Mem. 30:3–28), including *Bayer Schering Pharma AG v. Sandoz, Inc.*, in which the court dismissed antitrust claims against a drug manufacturer upon finding that plaintiff failed to plead a market encompassing alternative drugs to treat certain indications. 813 F. Supp. 2d 569, 577 (S.D.N.Y. 2011). HCSC also attempts to discredit *Humana* (Opp. 7:5–11), which rejected the same ACTH-only market that HCSC proposes. But, contrary to HCSC’s representation (Opp. 7:7), *Humana* did consider economic substitutability and recognized that medical substitutes *are* economic substitutes “relevant to the determination of a drug product market.” 2020 WL 3041309, at *4. The court also analyzed nearly identical allegations concerning cross elasticity of demand, finding that none of the allegations supported a claim that Mallinckrodt was able to raise prices exponentially without corticosteroids and other non-ACTH drugs taking away sales from Acthar. *Id.* at *6.

2. HCSC Fails to Allege Injury to Its Business or Property from any Reduction in Competition as a Result of the Synacthen Acquisition.

Just as HCSC’s allegations of an ACTH-only market obscure the variety of uses for and alternatives to Acthar, its presentation of Synacthen as a generic version of Acthar obscures any plausible outline of injury to HCSC—lower prices for Acthar in a “but for” world. Mem. 31:21–

33:18. HCSC contests this conclusion by conspicuously making express its construct of Synacthen being a generic version of Acthar that would have been immediately available to replace Acthar for any and all prescriptions. Opp. 7:13–8:10. HCSC, however, appropriately pleaded that Synacthen is not a generic version of Acthar but rather a synthetic ACTH that is *not* FDA approved for sale in the United States. Cmpl. ¶ 15. Thus, HCSC suffered no injury from Questcor’s acquisition of rights to Synacthen until such time as another purchaser would have obtained FDA approval for an indication for which Acthar has market power and Synacthen would have entered such a market in a manner causing a reduction in Acthar’s price. Mem. 32:11–19. HCSC has not so pleaded.

HCSC’s use of *Tawfilis v. Allergan, Inc.*, 157 F. Supp. 3d 853 (C.D. Cal. 2015), as a benchmark against which to assess the complaint’s allegations of injury (Opp. 8:11–9:2) reinforces Mallinckrodt’s point. There, Botox purchasers alleged both Botox’s market power in a U.S. market *for wrinkle treatments* and the excluded Botox alternative’s greater share of sales than Botox in foreign markets *for wrinkle treatments*. 157 F. Supp. 3d at 857–58. Here, HCSC would leave the Court to guess as to whether, for example, Synacthen is a plausible replacement for Acthar as the standard of care for infantile spasms in the U.S., and whether, for other indications, it would be one of several alternatives for “first line” treatment or an alternative to Acthar as a “last line” treatment.

And in *Tawfilis*, the plaintiffs made allegations regarding the prospects for, and potential timing of, the alternative neurotoxin’s FDA approval and sale in the United States. They alleged that the pathway to FDA approval was through a “Biologics License Application” providing for a “truncated clinical study timeline,” which does not involve “expensive and time consuming genetic toxicology studies, carcinogenicity studies, drug interaction studies, and pharmacokinetic studies in humans . . . [that] are required for drugs and biologics to treat or cure human diseases,” and that the alternative neurotoxin would have been on the market within two years of its regulatory approval. *Id.* at 857–58 (internal quotations omitted). Here, Synacthen must go through those extensive and time-consuming studies in humans, and it must do so for each indication for which it is to obtain FDA approval. Moreover, HCSC does not even dispute that the real world conclusively establishes that its supposed injuries in the “but for” would pre-date by *six years* any conceivable FDA approval for Synacthen or that it pleads no facts as to when such approval can be expected (Mem. 33:8–18).

Nor can HCSC invoke a more forgiving standard. HCSC would distinguish Mallinckrodt's analogous authorities on the ground that the "complaints [] failed altogether to allege competing products could be brought to market, because regulatory approval was lacking." Opp. 9 n.3. But HCSC's complaint fails in exactly the same way. HCSC also relies on a concurring opinion in *Biocad JSC v. F. Hoffmann-La Roche*, 942 F.3d 88 (2d Cir. 2019), to contend that the timing and manner of Synacthen's prospective FDA approval need not be part of the Court's assessment of its allegations of injury. Opp. 9 n.3. The Honorable Robert Katzmann concurred, however, to note his disagreement that the facts pleaded must make FDA approval "probable" as opposed to just plausible. 942 F.3d at 101. And he recognized that "the probability of FDA approval should be considered as a significant . . . factor in a broader preparedness inquiry at the motion-to-dismiss stage." *Id.* As pleaded, HCSC's claim fails to address this factor.

3. Thirty-Two Claims Are Barred by the Statutes of Limitations.

HCSC's challenge to the seven-year-old Synacthen acquisition is barred by the four-year limitation periods of the Cartwright Act (and UCL) and 31 other states' antitrust laws.⁵ Mem. 33:21–22; Def. RJN Ex. O; Opp. RJN 8:6–22. HCSC's dispute rests on two flawed premises.

The first is that Mallinckrodt's alleged failure to develop Synacthen, not just the acquisition itself, is subject to antitrust scrutiny. HCSC argues that Mallinckrodt's alleged unilateral decision to "shelve" Synacthen constitutes a continuing violation of the antitrust laws (*id.* at 23:20–22) and that Mallinckrodt's allegedly false statements "that it would develop and seek FDA approval of Synacthen" toll the limitations periods for fraudulent concealment until January 2017 (*id.* 22:11–12 (quoting Cmpl. ¶ 177) & n.14). But unilateral decisions about whether to develop a new product are *not* subject to antitrust scrutiny.⁶ And HCSC does not even suggest that the license agreement contains a provision requiring Mallinckrodt to "shelve" Synacthen. The gravamen of HCSC's antitrust claim is the acquisition. HCSC ignored this point. Mem. 34:16–20.

⁵ Mallinckrodt has identified a ground for statutory tolling under Oregon and New York law, and HCSC's invocation of *American Pipe* saves claims under the acts with five-year limitations periods (Maine, Montana, Vermont, and Wisconsin).

⁶ *Oahu Gas Serv., Inc. v. Pac. Res., Inc.*, 838 F.2d 360, 369 (9th Cir. 1988) ("[P]roduct innovation cases ha[ve] . . . rejected antitrust liability for a monopolist's decision about . . . whether to market new products."); *GAF Corp. v. Eastman Kodak Co.*, 519 F. Supp. 1203, 1231 (S.D.N.Y. 1981) (reasoning that scrutiny would have a "chilling effect on innovation and research not envisioned").

1 HCSC urges a contrary view by arguing that it is suffering a continuing *harm* by paying
 2 supracompetitive prices because of an allegedly illegally-maintained monopoly. Opp. 22:14–23:11.
 3 But the continuing violation doctrine applies to “[a]llegations of a pattern of reasonably frequent
 4 and similar acts [that] may, in a given case, justify treating the acts as an indivisible course of
 5 conduct actionable in its entirety.” *Aryeh v. Canon Bus. Sols., Inc.*, 55 Cal. 4th 1185, 1198 (2013)
 6 (refusing to apply doctrine to discrete unlawful acts with continuing harms). And courts have
 7 rejected HCSC’s theory in purchaser challenges to acquisitions. *Z Techs. Corp. v. Lubrizol Corp.*,
 8 753 F.3d 594, 558, 603 (6th Cir. 2014) (“The continuing violations doctrine does not apply to price
 9 increases following a merger or acquisition.”); *Midwestern Mach. Co. v. Nw. Airlines, Inc.*, 167
 10 F.3d 439, 440 (8th Cir. 1999);⁷ *see also* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* §
 11 320c4 (4th ed. 2020) (“[I]f the monopoly is created by a single identifiable act and is not perpetuated
 12 by an ongoing policy, the statute of limitation runs from the time of commission of that act.”).

13 HCSC’s second error is to invoke tolling based on class-action challenges to the Synacthen
 14 acquisition (Opp. 20:8–15), but the only challenge filed before the June 2017 expiration of its claims
 15 is *City of Rockford v. Mallinckrodt ARD, Inc.*, No. 3:17-cv-50107 (N.D. Ill. Apr. 6, 2017), and
 16 HCSC was not a member of the class as originally proposed. *Compare* Cmplt. ¶ 124, No. 3:17-cv-
 17 50107 (N.D. Ill., Apr. 6, 2017), Dkt. No. 1 (defining the class to be “self-funded entities”), *with*
 18 Cmplt. ¶¶ 17–19 (alleging that HCSC is a provider of fully-funded health plans, an administrator
 19 of public benefits, and an administrator of private plans on behalf of self-insured customers). This
 20 detail precludes Humana’s reliance on “*American Pipe* tolling.” *Perkin v. San Diego Gas & Elec.*
 21 *Co.*, 225 Cal. App. 4th 492, 492 (2014).

22 IV. CONCLUSION

23 For these reasons, the Demurrer and Motion to Strike should be granted.

24
 25 ⁷ HCSC attempts to distinguish *Midwestern Machinery* on the ground that it involved an alleged
 26 violation of the Clayton Act’s Section 7 as opposed to Sherman Act Section 2 (Opp. 23:12–19), but
 27 under either provision the acquisition is the violation; thus *Z Technologies* applied the four-year-
 28 from-acquisition rule to a purchaser’s Section 2 case. To the extent *In re Evanston Northwest Healthcare*, 2008 WL 2229488 (N.D. Ill. May 29, 2008), reflects a different outcome, its reasoning
 too rests on a misunderstanding that notice of the anticompetitive nature of an acquisition depends
 on knowledge of intent (*id.* at *4). Also of note, HCSC does not even respond to Mallinckrodt’s
 observation (Mem. n.11) that neither the Cartwright Act nor the Unfair Competition Law prohibit
 monopolization.

1 Dated: July 21, 2020

Respectfully Submitted,

2 **ARNOLD & PORTER KAYE SCHOLER LLP**

3
4
5 By: 
6 Sonia Kuester Pfaffenroth

7 *Attorneys for Defendant*
8 *Mallinckrodt ARD LLC and*
9 *Mallinckrodt plc*

PROOF OF SERVICE

1. I am over eighteen years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 777 South Figueroa Street, Forty-Fourth Floor, Los Angeles, California 90017-5844.
2. On **July 21, 2020**, I served the following document(s) with a hearing date and judicial assignment that were subsequently vacated, and on **July 21, 2020**, I served the same following documents with an updated hearing date and judicial assignment:

REPLY IN SUPPORT OF THE DEFENDANT MALLINCKRODT ENTITIES' DEMURRER AND MOTION TO STRIKE**REPLY RE REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF THE DEFENDANT MALLINCKRODT ENTITIES' DEMURRER AND MOTION TO STRIKE**

3. I served the document(s) on the following person(s):

[SEE ATTACHED SERVICE LIST]

4. The documents were served by the following means:

☐ **By U.S. Mail.** I enclosed the document(s) in a sealed envelope or package addressed to the person(s) at the address(es) in Item 3 and **(check one)**:

☐ deposited the sealed envelope with the United States Postal Service, with the postage fully prepaid.

☐ placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for mailing. On the same day the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

I am employed in the county where the mailing occurred. The envelope or package was placed in the mail at Los Angeles, California.

☐ **By Overnight Delivery/Express Mail.** I enclosed the documents and an unsigned copy of this declaration in a sealed envelope or package designated by **[name of delivery company or U.S. Postal Service for Express Mail]** addressed to the persons at the address(es) listed in Item 3, with **[Express Mail postage or, if not Express Mail, delivery fees]** prepaid or provided for. I placed the sealed envelope or package for collection and delivery, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for express delivery. On the same day the correspondence is collected for delivery, it is placed for collection in the ordinary course of business in a box regularly maintained by **[name of delivery company or U.S. Postal Service for Express Mail]** or delivered to a courier or driver authorized by **[name of delivery company]** to receive documents.

☐ **By Messenger Service.** I served the documents by placing them in an envelope or package addressed to the persons at the address(es) listed in Item 3 and providing them to a professional messenger service for service. (See attached Declaration(s) of Messenger.)

- ☐ **By Facsimile Transmission.** Based on an agreement between the parties to accept service by facsimile transmission, which was confirmed in writing, I faxed the document(s) and an unsigned copy of this declaration to the person(s) at the facsimile numbers listed in Item 3 on **July 21, 2020**, at [type time]. The transmission was reported as complete without error by a transmission report issued by the facsimile machine that I used immediately following the transmission. A true and correct copy of the facsimile transmission report, which I printed out, is attached hereto.
- ☒ **By Electronic Service (E-mail).** Based on California Rule of Court 2.251(c)(3), or on a court order, or on an agreement of the parties to accept service by electronic transmission, I transmitted the document(s) to the person(s) at the electronic notification address(es) listed in Item 3 on **July 21, 2020**.
- ☐ **Via Court Notice of Electronic Filing.** The document(s) will be served by the court via NEF and hyperlink to the document(s). On **July 21, 2020**, I checked the CM/ECF docket for this case or adversary proceeding and determined that the person(s) listed in Item 3 are on the Electronic Mail Notice List to receive NEF transmission at the email addresses indicated in Item 3 [or on the attached service list, if applicable].
- ☐ **Via Electronic Notification.** The document(s) will be served via electronic notification on **July 21, 2020** on the person(s) listed in Item 3 at the email addresses indicated in Item 3 [or on the attached service list, if applicable].
- ☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.
- ☐ **FEDERAL:** I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Dated: **July 21, 2020**.

Signature: Kathryn Jensen

Type or Print Name: Kathryn Jensen

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Health Care Service Corp. v. Mallinckrodt ARD LLC, etc., et al.
Alameda Superior Court Case No. RG20056354

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**REPLY RE REQUEST FOR
JUDICIAL NOTICE IN SUPPORT
OF THE DEFENDANT
MALLINCKRODT ENTITIES'
DEMURRER AND MOTION TO
STRIKE**

Date: August 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Res. Nos. 2179414 & 2179416

Action Filed: February 27, 2020

ENDORSED
FILED
ALAMEDA COUNTY

JUL 21 2020

CLERK OF THE SUPERIOR COURT

Anita Dhir

COPY

BY FAX

Defendants Mallinckrodt ARD LLC (“Mallinckrodt”) and Mallinckrodt plc (collectively, “Defendants”) respectfully submit this Reply regarding their May 28, 2020 Request for Judicial Notice (“RJN”) in Support of their Demurrer to, and accompanying Motion to Strike as to, Plaintiff Health Care Services Corporation (“HCSC”)’s Complaint. Defendants have requested the Court to take judicial notice of the fact and contents of 15 documents, which are attached as Exhibits A through O to the RJN. In its June 23, 2020 Opposition to the RJN (“RJN Opp.”), HCSC objects to the admission into the record of three categories of the documents that are subject to Defendants’ RJN. HCSC’s objections lack merit and underscore the damage these documents do to HCSC’s claims.

A. This Court May Take Judicial Notice of the Existence and Contents of News Articles and Federal Register Entries and May Do So for Purposes Establishing HCSC’s Inquiry and Constructive Notice of Its Claims.

HCSC objects to Mallinckrodt’s request for judicial notice of RJN Exhibits A through D, which are:

- (1) the Department of Health and Human Services Office of Inspector General (“OIG”)’s Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, which was published in the Federal Register on November 22, 2005;
- (2) OIG Supplemental Special Advisory Bulletin on Independent Charity Patient Assistance Programs, which was published in the Federal Register on May 30, 2014 (“2014 SAB”);
- (3) an article titled *Too Close for Comfort*, published in *Barron’s* on October 19, 2013 and available online; and
- (4) an article titled *Drug Maker’s Donations to Co-Pay Charity Face Scrutiny*, published in *The New York Times* on December 18, 2013 and available online.

Opp. RJN 2:11–3:20. Defendants submit these documents because they demonstrate that by mid-2014 HCSC was on inquiry and constructive notice of its claims related to Mallinckrodt’s contributions to copay assistance funds operated by the Chronic Disease Fund (“CDF”) for Medicare beneficiaries. HCSC does not, and cannot, actually contest that the Court may take judicial notice of the fact and content of these documents, which were either published in the Federal

1 Register (RJN at 4:4–8 (establishing that the Court shall take notice of documents published in the
2 Federal Register)) or by national media outlets (*id.* at 4:22–5:10 (establishing that the Court shall
3 take notice of documents not reasonably subject to dispute, such as news articles)).

4 HCSC attempts to avoid the damning effect of these documents on its claims by arguing that
5 Defendants are using the documents for an improper purpose—for the truth of the matter asserted.
6 Opp. RJN at 1:26–3:20. But the well-established rule is that establishing inquiry notice or
7 constructive knowledge is a permissible use of documents judicially noticed for their existence and
8 content. *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 408 nn.6–7 (1999) (rejecting that plaintiffs could
9 not have known to name defendant in their complaint because a controversy about defendant had
10 already “arisen in the popular press”); *McKelvey v. Boeing North Am., Inc.*, 74 Cal. App. 4th 151,
11 162 n.13 (1999) (“Since plaintiffs did not dispute the accuracy of the relevant facts—that is, that the
12 articles were published . . . there is no reason the matter could not have been resolved by demurrer.”).
13 As the court recognized in *McKelvey*, when admitting articles for purposes of constructive notice,
14 “[t]he accuracy of the reporting is irrelevant” because the court is not taking notice of the truth of a
15 document on an issue of *fact* in dispute. 74 Cal. App. 45 at 162. HCSC largely ignores these cases
16 and Defendants authorities (cited at RJN 4:25–5:5).¹

17 Unsurprisingly, the cases on which HCSC relies for its statement of a contrary rule are
18 inapposite. HCSC cites *Unruh-Haxton v. Regents of University of California*, 162 Cal. App. 4th
19 343, 365 (2008), for the proposition that a court cannot accept the contents of judicially noticed
20 documents to establish a plaintiff’s constructive suspicion of its claims. Opp. RJN at 2:15–17.
21 *Unruh-Haxton*, however, simply held on the record before it that judicially noticed “widespread
22 media coverage” of defendant’s misconduct was not alone sufficient on a demurrer to show
23 plaintiffs were on inquiry notice of their claims because the coverage could not “conclusively refute
24 the [plaintiffs’] allegations they either (1) did not see or read the media coverage, or (2) saw the
25

26 ¹ HCSC attempts to discredit this holding from *McKelvey* on the ground that *Lopez v. Sony*
27 *Electronics, Inc.*, 5 Cal. 5th 627 (2018), recognized that *McKelvey* was partially abrogated by
28 statute. Opp. 22 n.13. But the Legislature did not abrogate the general principles that *McKelvey*
applied; it prevented their application only to toxic tort claims. 5 Cal. 5th at 633 n.3 (quoting Civ.
Pro. Code § 340.8(c)(2)).

1 publicity, but failed to discover any wrongdoing.” 162 Cal. App. 4th at 365. Here, in contrast,
 2 Defendants show that HCSC is charged with knowledge of the OIG’s 2014 SAB, which placed
 3 HCSC on inquiry notice of its claims, and that HCSC would have quickly confirmed the existence
 4 of its claims upon a cursory search for information on copay assistance for Acthar patients and a
 5 review of the hits, including news reporting on the Acthar-only nature of certain CDF funds for
 6 Medicare beneficiaries. Mem. re Demurrer & Mot. to Strike 23:1–16; Reply re Demurrer & Mot.
 7 to Strike 9:5-10:18.

8 HCSC’s reliance on *Richtek USA, Inc. v. uPI Semiconductor Corp.*, 242 Cal. App. 4th 65
 9 (2015), is similarly misplaced. *Richtek* rejected the defendants’ effort to use the plaintiffs’
 10 allegations in a prior case to contradict the plaintiffs’ pending allegations that they did not have
 11 actual knowledge of the defendants’ misconduct until shortly before filing the pending suit. 242
 12 Cal. App. 4th 651, 659–60 (overturning a demurrer where “the trial court used the allegations in the
 13 Taiwan complaints to conclude that appellants *had* knowledge of respondents’ misappropriation in
 14 2007”) (emphasis added). Mallinckrodt does not seek to establish that HCSC had *actual* knowledge
 15 of its claims before HCSC claims to have discovered them; Mallinckrodt argues that judicially
 16 noticeable facts put HCSC on *inquiry* notice and *constructive* knowledge of its claims as a matter
 17 of law. Mem. re Demurrer & Mot. to Strike 23:1–18. There is no conflict of fact to resolve
 18 regarding HCSC’s alleged date of actual discovery because the doctrine of fraudulent concealment
 19 tolls a claim only until the “plaintiff, by the exercise of reasonable diligence, *should* have discovered
 20 it,” *Bernson v. Browning-Ferris Indus.*, 7 Cal. 4th 926, 931 (1994) (emphasis added), regardless of
 21 when he actually discovered it.

22 HCSC also cites *Voris v. Lampert*, 7 Cal. 5th 1141, 1147 (2019), and *People ex rel. Lockyer*
 23 *v. Shamrock Foods Co.*, 24 Cal. 4th 415 (2000), for the proposition that news articles cannot
 24 establish “when HCSC was on notice of certain allegations.” Opp. RJN 3:1–6. But, the *Voris* court
 25 declined a request to take judicial notice of four newspaper articles and a criminal indictment
 26 *because the plaintiff offered them for the purposes of establishing that the plaintiff had pleaded a*
 27 *cognizable claim for conversion of wages.* 7 Cal. 5th at 1147, n.5. The *Shamrock* court declined to
 28

1 take judicial notice of news articles that it found irrelevant to the material issues of the case. 24 Cal.
2 4th at 422, n.2.

3 **B. The Court Can Judicially Notice a DOJ Press Release and Full JAMA Article.**

4 HCSC also objects to the Defendants' request that the Court judicially notice two documents
5 from which HCSC selectively quotes in the Complaint in an effort to support its conclusion that
6 payments to doctors were bribes as opposed to legitimate payments for speaking and research.
7 Neither has merit.

8 (1) HCSC objects to Defendants' request that the Court take judicial notice of the United
9 States Department of Justice's press release regarding its September 2019 settlement with
10 Mallinckrodt (RJN Opp. 3:23–4:12), which HCSC references in the Complaint as being a settlement
11 of claims "related to [Mallinckrodt's] physician kickback scheme" (Cmplt. ¶ 161, n.31). While
12 HCSC offers conclusory allegations that the supposed scheme has been running from 2011 to the
13 present, the DOJ describes the allegations on which its settlement is based as being that 12 Questcor
14 sales representatives went too far when providing meals and entertainment to certain doctors
15 between 2009 and 2013 (RJN Ex. H). The DOJ's description of its allegations sheds light on the
16 overreach of HCSC's allegations; and so HCSC objects to including that description in the record.
17 But HCSC offers no basis for its objection, and the DOJ's press release is clearly judicially
18 noticeable as official executive agency action under Evid. Code § 452(c). RJN 4:9–13. Rather,
19 HCSC offers a misplaced and inaccurate discussion of the merits, arguing that Defendants offer the
20 press release to prove that "there was no actionable misconduct concerning sales representatives
21 from 2014 to the present." RNJ Opp. 4:6–7. In fact, Defendants offer the press release for a different
22 purpose: to establish that the settlement contains no admission of liability, that the Complaint's
23 reference to the settlement, therefore, should be stricken, and at a minimum, the settlement cannot
24 plausibly support HCSC allegations that payments between 2014 and the present were for improper
25 purposes. The DOJ's own official statements, not Mallinckrodt's or HCSC's, state the scope of
26 DOJ's contentions, and those official statements and action by the agency may be judicially noticed
27 by the Court.
28

(2) HCSC objects to Defendants' request that the Court take notice of a study published in the Journal of the American Medical Association's ("JAMA") Network Open in 2018 on Mallinckrodt's payments to doctors and Acthar prescriptions (RJN Ex. I). Again, HCSC's objection is based on an inaccurate description regarding the use to which Defendants put the article. Defendants offer the full article because HCSC selectively references and quotes from the 2018 JAMA study in its Complaint to support its bribery allegations (Cmplt. ¶ 158). Defendants offer the full article to show that on its face the study does not make plausible HCSC's allegations that payments to doctors were bribes because the study's authors admit in their report that their study does *not* establish a causal connection between the payments and prescription rates. Mem. ISO Demurrer & Mot. to Strike 25:24–26:2. HCSC offers no dispute as to the accuracy of the copy of the study that Defendants submitted, and therefore, it has no basis to object. *Ingram v. Flippo*, 74 Cal. App. 4th 1280, 1285 n.3 (1999) (taking judicial notice of a letter and media release summarized and quoted in plaintiff's complaint despite not being attached to the complaint); *Salvaty v. Falcon Cable Television*, 165 Cal. App. 3d 798, 800 n.1 (1985) (holding that defendants were entitled to present the court with a complete document when it was referred to repeatedly in the complaint).

C. The Court Can Reference Defendants' Tables of Out-of-State Authorities.

Defendants included in their Request for Judicial Notice five tables listing out-of-state authorities relating to HCSC's nine counts under more than 40 states' laws. RJN Exhibits K–O. HCSC objects that they are, at least in part, not appropriate topics for judicial notice. But Defendants offer the tables for the Court's convenience in assessing common grounds across all states' laws and for efficient disposition of specific counts in their entirety or, at least, of categories of alleged misconduct. The tables can serve that purpose whether judicially noticed or not.

While HCSC contends that the tables are incomplete or offer "cherry-picked" quotations (RJN Opp. 5:8–11), HCSC does not dispute the accuracy of Exhibits L–O in any way, and it disputes Exhibit K, which lists authority as to the lack of a private enforcement mechanism for (or other threshold legal defenses to claims under) the 40 states' insurance-fraud statutes that HCSC invokes in Count VII of the Complaint, only as to the Kentucky, California, Florida, and New Jersey insurance fraud statutes. As to each:

1 **Kentucky.** Defendants agree with HCSC that, after the court decision on which Defendants
 2 rely, Kentucky repealed its statutory requirement of a conviction before private enforcement under
 3 Ky. Rev. Stat. § 304.47-020. RJN Opp. 6:3–7. However, Kentucky’s insurance fraud statute is
 4 subject to a five-year limitation period from the date HCSC had actual or constructive notice of its
 5 injury or claim, Ky. Rev. Stat. § 413.120(2), and thus, HCSC’s insurance fraud claim as it relates to
 6 copay assistance is time-barred under the Kentucky statute. Mem. re Demurrer & Mot. to Strike
 7 22:1–24:4; Reply re Demurrer & Mot. to Strike 9:1–10:12. And to the extent the claim is based on
 8 alleged payments to doctors, the claim fails for failure to plead facts supporting the conclusion that
 9 the payments were bribes or caused injury to HCSC. Mem. re Demurrer & Mot. to Strike 24:25–
 10 26:27; Reply re Demurrer & Mot. to Strike 11:5–11:25.

11 **California.** Defendants also agree with HCSC that, although HCSC did not so plead its
 12 claims, a private party may bring an action under California’s Unfair Competition Law (UCL) on
 13 the basis of a violation of the state’s Insurance Code. RJN Opp. 6:11–18. Even if HCSC were to
 14 so plead its claim, the claim is subject to a four-year limitation period under the UCL and thus time-
 15 barred as it relates to copay assistance claims. Bus. & Prof. Code § 17208. And like the claim
 16 under Kentucky’s insurance fraud statute, the allegations are insufficient to support the claim to the
 17 extent based on payments to doctors.

18 **Florida.** HCSC incorrectly argues that Florida’s insurance fraud statute permits an insurer
 19 to pursue a private right of action without a criminal adjudication of guilt for insurance fraud by
 20 first citing a case that in fact supports the criminal conviction requirement. RJN Opp. 6:19–22;
 21 *Molina v. Provident Life & Accident Ins. Co.*, 18-24413-CV, 2019 WL 3429889, at *3–4 (S.D. Fla.
 22 May 31, 2019), *report and recommendation adopted*, 18-24413-CIV, 2019 WL 7937935 (S.D. Fla.
 23 June 27, 2019) (holding that both private enforcement provisions of Fla. Stat. § 817.234 require that
 24 the defendant be adjudicated guilty in violation of the statute before a party may bring a private
 25 cause of action). The second case cited by HCSC does nothing to call the criminal conviction
 26 requirement in Fla. Stat. § 817.234 into question, RJN Opp. 6:22–26, as it interprets an entirely
 27 different provision of Florida’s insurance code, Fla. Stat. § 627.736(12), and merely holds that the
 28

1 provision does not preempt other common law claims. *Nationwide Mut. Co. v. Ft. Myers Total*
2 *Rehab Ctr., Inc.*, 657 F. Supp. 2d 1279, 1287 (M.D. Fla. 2009).

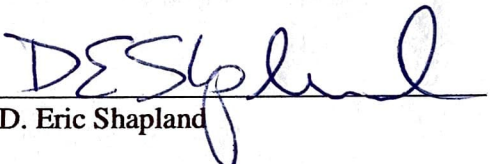
3 ***New Jersey.*** While compliance with the procedures set forth in the New Jersey Insurance
4 Fraud Act is not an element of the statutory claim (RJN Opp. 7:2–9), HCSC does not challenge the
5 accuracy of any other defense to this claim raised by Defendants—i.e., that HCSC has failed to
6 plead the claim with particularity or allege actual injury from the alleged violation (RJN Ex. K at
7 129).

8 Dated: July 21, 2020

Respectfully Submitted,

9
10 **ARNOLD & PORTER KAYE SCHOLER LLP**

11 By:



12 D. Eric Shapland

13 *Attorneys for Defendants*
14 *Mallinckrodt ARD LLC and*
15 *Mallinckrodt plc*
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[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
 Mallinckrodt ARD Inc., f/k/a Questcor
 Pharmaceuticals, Inc.), and
 MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

Hon. Stephen Kaus

CASE MANAGEMENT CONFERENCE
STATEMENT FOR AUGUST 5, 2020
CASE MANGEMENT CONFERENCE

I. INTRODUCTION

Plaintiff Health Care Service Corporation and Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (“Mallinckrodt”) have met and conferred in advance of the Case Management Conference scheduled for August 5, 2020. They refer the Court to a more detailed Case Management Conference Statement that the parties prepared and filed in advance of a Case Management Conference that was scheduled for Jun 23, 2020, which addresses the issues that are ripe for discussion at the August 5, 2020 Conference.

II. AGREED UPON CASE MANAGEMENT ISSUES

A hearing on Defendant’s demurrer and motion to strike is scheduled for August 5, 2020, at 3 PM in Department 19, to coincide with this conference. As noted in a previously submitted case management statement, the parties have met and conferred and agree to a staged approach to discovery, under which they conduct document discovery and then reconvene for a case management conference in November, when more is known about the scope of the case after a ruling on the pending motions and the impact of the pandemic on the pace of litigation, to schedule subsequent stages of the case.

In the event the Court is inclined to set a more complete case schedule at this time, the parties jointly and tentatively propose the following schedule:

Date	Event
June 30, 2021	Fact discovery deadline
July 2021	Parties to conduct mediation at a time and place to be determined
September 22, 2021	Plaintiff to produce expert reports
November 19, 2021	Defendants to produce expert reports
January 20, 2022	Summary judgment or summary adjudication deadline
TBD	Trial

Mallinckrodt has provided HCSC with a proposed Protective Order regarding Confidentiality and HCSC has provided comments, and HCSC has provided Mallinckrodt with a stipulation regarding

expert discovery, which Mallinckrodt has under consideration. Should the parties not agree on certain aspects of these orders, they will meet and confer to resolve their differences and, if they cannot, they will abide by the Court's procedures to resolve their differences.

The parties have discussed the use of alternative dispute resolution ("ADR") and mediation services, as provided for the Court's May 21, 2020 Notice of Reassignment. The parties have proposed provision for private mediation as part of their proposed case schedule.

A. Plaintiff's Position on Additional Case Management Issues and Discovery

HCSC believes that periodic status conferences will help with the progress of this litigation. HCSC proposes that the Court conduct bi-monthly status conferences, and that the parties submit a statement outlining any outstanding issues one week before any scheduled conference. In light of the COVID-19 pandemic, which has impacted the Court and parties alike, HCSC proposes to conduct status conferences by video conference or some other method convenient to the Court.

B. Defendants' Position on Additional Case Management Issues and Discovery

Mallinckrodt urges the Court to carefully consider the pending demurrer and motion to strike and the parties' proposal to stage discovery and wait until pleading motions are resolved before establishing a case schedule beyond document discovery in this matter. HCSC challenges five categories of conduct alleging nine separate counts under the laws of over forty different states, and it places at issue all Acthar prescriptions that HCSC covered back to 2011. As Mallinckrodt has explained its briefing on the pending demurrer and motion to strike, HCSC's opposition contains telling admissions regarding flaws in the theories under which each category of alleged misconduct supposedly supports any claim for relief, and courts addressing similar claims by other Acthar payors have narrowed or dismissed the actions on the pleadings.

With respect to HCSC's proposal to schedule regular conferences with the Court, Mallinckrodt draws some confidence from the parties' ability to cooperate informally to date in this action, and it believes that they will be able to informally resolve many discovery disputes as they arise. Mallinckrodt therefore does not think the Court should dedicate some of its limited resources to the resolution of disputes that have not yet arisen.

1 Dated: July 29, 2020

Respectfully submitted:

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3 **KONECKY LLP**

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EXHIBIT 50

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Attorneys for Plaintiffs

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiffs,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendant.

Case No. RG20056354

PROOF OF SERVICE

PROOF OF SERVICE

I, Kelle J. Winter, declare the following:

I am over the age of eighteen years and not a party to the within entitled action. I am employed at Schneider Wallace Cottrell Konecky LLP located at 2000 Powell Street, Suite 1400, Emeryville, CA 94608.

On **July 29, 2020**, I served the following document(s) described as:

- **CASE MANAGEMENT CONFERENCE STATEMENT FOR AUGUST 5, 2020 CASE MANGEMENT CONFERENCE**

on the following interested party(s):

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☒ **BY ELECTRONIC SERVICE** by electronically mailing a true and correct copy in PDF format through SWCK's electronic mail system to the email address(s) set forth above.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on July 29, 2020, at Scottsdale, Arizona.

/s/ Kelle J. Winter
Kelle J. Winter

EXHIBIT 51

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
 Mallinckrodt ARD Inc., f/k/a Questcor
 Pharmaceuticals, Inc.), and
 MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

Hon. Stephen Kaus

Date: August 19, 2020

Time: 3:00 P.M.

**NOTICE OF SUPPLEMENTAL
 AUTHORITY**

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

Plaintiff Health Care Service Corp. hereby provides notice that on August 14, 2020 Judge Dale S. Fischer of the U.S. District Court for the Central District of California issued an order, attached as Exhibit A, granting in part and denying in part Defendant Mallinckrodt ARD LLC and Mallinckrodt PLC's motion to dismiss. *See Humana Inc. v. Mallinckrodt ARD LLC, et al.*, Case No. 2:19-cv-06926-DSF-MRW (C.D. Cal. Aug. 14, 2020) ("*Humana*"). The *Humana* ruling has several applications to Defendants' pending demurrer and motion to strike.

First, Judge Fischer's ruling supports the arguments Plaintiff makes in its opposition brief that it has sufficiently pled the existence of an antitrust market. Opp. Br. at 5:25-7:11; Compl. ¶¶ 6, 185-86 (Acthar a drug of "last resort" that is not a substitute for "earlier line" drugs); *id.* at ¶¶ 77-81 (Acthar sold in "specialty" pharmacies); *Humana* Slip Op. at 6-11). The ruling also accepts the arguments Plaintiff makes here concerning the sufficiency of its allegations of antitrust injury. Opp. Br. at 7:15-9:2; *Humana* Slip Op. at 17 ("the date another bidder could have or would have brought Synacthen to market is a factual question not best resolved at the motion to dismiss stage. Moreover, discovery might reveal that, had it not won the bid, Defendant would have started lowering its prices prior to Synacthen's market entrance in anticipation of future competition.").

Second, Judge Fischer's ruling also supports certain of Plaintiff's arguments that its claims are timely. Judge Fischer adopts the "continuing violation" theory of tolling, rejecting the argument that *Humana*'s challenge to the Synacthen acquisition accrued when the transaction was complete. See *Humana* Slip Op. at 22 ("the statute of limitations does not bar Plaintiff from asserting claims based on harms flowing from the alleged anticompetitive license payments made to Novartis during the limitations period"); Opp. Br. at 22:15-24:4.

Finally, Judge Fischer rejected the theory of fraudulent concealment advanced by *Humana* with respect to its claims for Section 2 of the Sherman Act. *Humana* Slip Op. at 18-19. As an initial matter, this ruling can provide no basis for dismissal here because *Humana*'s antitrust claims were nevertheless preserved by the continuing violation doctrine. Slip Op. at 19-22. Moreover, Plaintiff relies on additional factual allegations concerning its monopolization claims, including that Defendants used exclusive distribution, which is not alleged to have ceased by 2013 or at any other

time. *See* Opp. Br. 4:8-24. Plaintiff does not allege that the bad acts supporting its monopolization claims ceased by 2013. Moreover, Judge Fischer's ruling does not prevent the application of fraudulent concealment to Plaintiff's fraud-based claims, premised on Defendants' repeated representations they were following the law (Opp. Br. at 22:6-13), as noted by the order. Slip Op. at 19 n. 9 ("The facts necessary to put Plaintiff on inquiry notice of the RICO claims differs materially from the types of facts that would put Plaintiff on inquiry notice of the antitrust claims.").

Judge Fischer's order confirms that, as argued in Plaintiff's opposition to Defendants' motion to dismiss more generally, a demurrer is procedurally improper because it will not "either will result in a complete dismissal or ... significantly narrow the scope of discovery." Dept. 19 General Guidelines at 2.

Dated: August 17, 2020

Respectfully submitted:

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p. 774

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EXHIBIT 52

EXHIBIT A

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

HUMANA INC.,
Plaintiff,

v.

MALLINCKRODT ARD LLC
(f/k/a Mallinckrodt ARD Inc., f/k/a
Questcor Pharmaceuticals, Inc.),
Defendant.

CV 19-6926 DSF (MRWx)

Order GRANTING in Part and
DENYING in Part Defendant's
Motion to Dismiss (Dkt. 65)

Defendant Mallinckrodt ARD LLC moves to dismiss (a) Counts I, II & III (federal and state antitrust laws) in their entirety, or at least to the extent based on any state's antitrust law except Maine, Vermont, or Wisconsin law; (b) Counts IV & V (RICO), Count VI (unfair competition law), Count VII (state consumer fraud and deceptive trade practices acts), and Count VIII (state insurance fraud statutes) to the extent based on allegations regarding co-pay assistance programs; (c) Count IX (tortious interference with contract) in its entirety; and (d) Count VII (state insurance fraud statutes) to the extent asserted under Kentucky or New Jersey law as alleged in Plaintiff Humana Inc.'s Second Amended Complaint (SAC). Dkt. 65-1 (Mot.). Plaintiff opposes. Dkt. 71 (Opp'n). The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15. For the reasons stated below, the motion is GRANTED in part and DENIED in part.

I. FACTUAL AND PROCEDURAL BACKGROUND

Defendant produces H.P. Acthar Gel (Acthar), a drug that has been available in the United States since it was approved by the FDA in 1952. Dkt. 60 (SAC) ¶¶ 2, 44. Plaintiff operates or administers Medicare Part D plans on behalf of federal and state governments and provides coverage for prescription drugs, including Acthar, through other plans. Id. ¶ 39. Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. Id. ¶ 41. Acthar is approved to treat exacerbations of multiple sclerosis (MS) as well as other diseases and disorders. Id. ¶ 45. However, for many of these conditions, Acthar is not the “first-line treatment.” Id. ¶ 46. Cheaper, non-ACTH drugs are used to treat the same indications. Id. ¶¶ 49-50, 60. Infantile spasms is the only condition for which Acthar is the “first-line treatment.” Id. ¶ 51 n.4. There is only one other FDA-approved drug for infantile spasms. Id. ¶ 49 n.3. Acthar is the only long-acting ACTH drug approved for sale in the United States. Id. ¶ 61. Another ACTH drug, Synacthen, is approved for sale outside of the United States. Id. ¶ 70. Acthar is not marketed outside of the United States. Id.

Until 2001, when Defendant’s predecessor, Questcor, acquired worldwide rights to sell and manufacture Acthar for \$100,000, plus royalties, Acthar was priced more competitively with other anti-inflammatory drugs. Id. ¶ 47. At that time, because Acthar was expensive to produce and not the first-line treatment for most conditions, the prior manufacturer considered discontinuing production. Id. However, as soon as Questcor acquired the rights to sell Acthar, it increased the price from approximately \$40 per vial to nearly \$750 per vial. Id. ¶ 54. On August 27, 2007, Questcor further increased the price from \$1,650 to \$23,269 per vial. Id. ¶ 55. By 2018, the price had increased to \$38,892. Id. ¶ 56. Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from \$50 million to \$500 million. Id. ¶¶ 57-58. Humana itself paid for almost \$800 million worth of Acthar since 2001. See id. ¶ 86.

In 2010, Questcor established an MS Acute Exacerbation Fund (MS Fund) with Chronic Disease Fund, Inc. (CDF), a Texas-based charity. Id. ¶¶ 29, 97-98, 108. The MS Fund helped patients with government insurance, such as Medicare, with co-pays for Acthar. Id. ¶ 98. Although the donation agreement stated that the donated funds were generally for the treatment of patients with acute exacerbations of MS, in reality it did not provide co-pay assistance to purchase any other drugs. Id. In 2011, Questcor established a Lupus Exacerbation Fund (Lupus Fund) that was purportedly to provide co-pay assistance for “any medically appropriate therapy,” but in fact was used only to provide assistance for Acthar. Id. ¶ 100. In 2012, Questcor created a similar fund for rheumatoid arthritis (RA Fund). Id. ¶ 101. Between the time Questcor established the MS Fund in 2010 and 2013, Acthar sales for MS treatment nearly quadrupled. Id. ¶ 108.

In late 2012 and early 2013, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Id. ¶¶ 73-76. Questcor and three other companies (who were not disclosed) submitted serious bids. Id. The three other companies intended to develop Synacthen to compete with Acthar; Questcor had “inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer.” Id. ¶ 76. However, Questcor’s bid was the highest, at a minimum of \$135 million. Id. ¶¶ 77-78. Neither Questcor nor Defendant “made more than superficial efforts to pursue commercialization of Synacthen . . . to protect Acthar monopoly pricing.” Id. ¶ 81. In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen to treat infantile spasms and nephrotic syndrome in the United States. Id. ¶ 82.

On March 9, 2020, the Court granted Defendant’s motion to dismiss the antitrust claims and the tortious interference with contractual relations claim in the First Amended Complaint with leave to amend and denied the motion as to the remaining claims. Dkt. 57 (March Order). Defendant again seeks dismissal of the antitrust claims and tortious interference claims in their entirety, as well as

dismissal of the RICO claims, unfair competition claim, state consumer fraud and deceptive practices claims, and insurance fraud claims to the extent they are based on co-pay assistance programs. Defendant additionally seeks dismissal of the insurance fraud claims to the extent they are based on Kentucky or New Jersey law and 22 of the 25 state-law antitrust claims as barred by the statute of limitations.

II. LEGAL STANDARD

Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. “[W]hen ruling on a defendant’s motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.” Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam). However, a court is “not bound to accept as true a legal conclusion couched as a factual allegation.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). “Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” Id. (quoting Twombly, 550 U.S. at 557) (alteration in original) (citation omitted). A complaint must “state a claim to relief that is plausible on its face.” Twombly, 550 U.S. at 570. This means that the complaint must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678. There must be “sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively . . . and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.” Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011).

Ruling on a motion to dismiss is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not ‘show[n]’ – that the pleader is

entitled to relief.” Iqbal, 556 U.S. at 679 (alteration in original) (citation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

As a general rule, leave to amend a complaint that has been dismissed should be freely granted. Fed. R. Civ. P. 15(a). However, leave to amend may be denied when “the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.” Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986).

III. DISCUSSION

A. Antitrust Claims (Counts I through III)

Plaintiff alleges that Defendant has monopoly power in the market for “long-acting ACTH drugs in the United States” and that Questcor’s acquisition of the rights to develop and market Synacthen in the United States “restrained trade” in the relevant market and “eliminated [a] potential competitive threat” in order to “maintain its monopoly” so it can “stabilize or raise the price of Acthar to a higher level” and “suppress[] the output of long-acting ACTH drugs below the level of output” that would exist in a competitive market. SAC ¶¶ 140-42, 146-48. This conduct purportedly violates Sections 1 and 2 of the Sherman Antitrust Act and corresponding state antitrust laws.

“In order to state a Section 1 claim . . . plaintiffs must plead facts which, if true, will prove ‘(1) a contract, combination or conspiracy among two or more persons or distinct business entities; (2) by which the persons or entities intended to harm or restrain trade or commerce among the several States, or with foreign nations; (3) which actually injures competition,’” and “(4) that they were harmed by the defendant’s anti-competitive contract, combination, or conspiracy, and that this harm flowed from an ‘anti-competitive aspect of the practice under scrutiny.’” Brantley v. NBC Universal, Inc., 675 F.3d 1192, 1197 (9th Cir. 2012) (first quoting Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1046 (9th Cir. 2008); then quoting Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990)). Section 2 “targets ‘the willful acquisition or maintenance of [monopoly] power as distinguished from

growth or development as a consequence of a superior product, business acumen, or historic accident.” Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc., 555 U.S. 438, 448 (2009) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570 (1966)). “Simply possessing monopoly power and charging monopoly prices does not violate § 2.” Id. at 447-48.

1. Market Power

Both Section 1 and Section 2 claims depend on whether Plaintiff has sufficiently alleged Defendant has market power in a relevant antitrust market. Newcal Indus., Inc. v. Ikon Office Sol., 513 F.3d 1038, 1044 n.3 (9th Cir. 2008) (“The ‘relevant market’ and ‘market power’ requirements apply identically under the two different sections of the Act, meaning that the requirements apply identically to” both Section 1 and Section 2 claims and plaintiff’s “market allegations are either sufficient or insufficient for all [antitrust] claims.”). “An antitrust complaint therefore survives a Rule 12(b)(6) motion unless it is apparent from the face of the complaint that the alleged market suffers a fatal legal defect.” Id. at 1045. One such fatal defect is the failure of the alleged market to “encompass . . . all economic substitutes for the product.” Id. The Court previously dismissed Plaintiff’s antitrust claims, in part, for failing to allege a facially sustainable product market definition. March Order at 13.

Plaintiff now alleges that the relevant market is the market for “the sale of long-acting ACTH drugs in the United States.” SAC ¶¶ 140 (Section 2), 147 (Section 1). Plaintiff further alleges that Defendant’s product, Acthar, “represents 100% of th[at] sub-market.” Id. ¶ 60. Defendant contends that “the SAC . . . proposes yet another *even narrower* ACTH-only market that continues to exclude economic substitutes for Acthar described in Humana’s own complaint.” Mot. at 2.¹ This is true in some sense if each allegation is considered in a

¹ Although Defendant emphasizes that the proposed market definition is “even narrower” with the exclusion of short-acting ACTH, Defendant does not appear to dispute that short-acting ACTH drugs are reasonably excluded from the relevant market. See Mot. at 6 (addressing why Plaintiff must

vacuum. In addition to the many paragraphs identified in the March Order that remain materially unchanged, March Order at 6-7 (citing FAC ¶¶ 6, 13, 43, 46, 49, 57, 84, 147, 151), Plaintiff's amended complaint adds allegations that appear to contradict its proposed market, see, e.g., SAC ¶¶ 49-50 ("prednisone is approved by the FDA to treat all of the same diseases and disorders as Acthar" and "Acthar has similar pharmacodynamic effects as corticosteroids"); id. ¶ 49 ("Acthar has been compared to intravenous methylprednisolone for treatment of MS relapses and to prednisone for treatment of sarcoidosis"). However, Plaintiff has also added allegations in support of its claim that there is a "long-acting ACTH drug[] . . . submarket within a broader market for adrenal hormone drugs." Id. ¶ 89. And within these allegations, the Court concludes that Plaintiff has adequately alleged a long-acting ACTH submarket.

"To plead an antitrust claim based on a submarket, 'the plaintiff must be able to show (but need not necessarily establish in the complaint) that the alleged submarket is economically distinct from the general product market.'" Hicks v. PGA Tour, Inc., 897 F.3d 1109, 1121 (9th Cir. 2018) (quoting Newcal Indus., Inc. v. Ikon Office Sol., 513 F.3d 1038, 1045 (9th Cir. 2008)). A plaintiff can do so by alleging "industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." Id. (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)).

allege indication-based markets and acknowledging Plaintiff's allegation that "short-acting ACTH drugs are not included in the relevant market 'because there is no overlap in the medical conditions that the drugs are approved to treat or diagnose'" (citing SAC ¶ 52 n.6); id. at 11-12 ("Only for those indications for which Synacthen proves effective and safe could it even be considered a possible potential new entrant, as Humana admits when excluding from its proposed market definition 'short-acting ACTH drugs.'").

a. Industry or public recognition of the submarket as a separate economic entity

Plaintiff alleges that “[l]ong-acting ACTH drugs are recognized by Mallinckrodt, medical providers, and the public as differentiated from other adrenal hormone drugs.” SAC ¶ 89.a.; see also id. ¶ 50 (“Acthar . . . appears to be viewed by certain providers or patients as distinct from corticosteroids.”). For example, “the widely-used First Data Bank (FDB) drug database” classifies corticosteroids like prednisone in a separate Therapeutic Class from Acthar and other ACTH drugs. Id. ¶ 52. Additionally, Defendant has acknowledged in its public filings that Acthar “has limited direct competition due to the unique nature of the product.” Id. ¶ 61.

On the other hand, Plaintiff alleges that Defendant has “aggressively marketed” “studies . . . that claim to show clinical evidence supporting the superiority of Acthar compared with corticosteroid drugs.” SAC ¶ 51. However, this seems to support, rather than refute, the idea that Acthar and corticosteroids are in the same market. See Hicks, 897 F.3d at 1122 (“claims of increased effectiveness” of products in the proposed submarket does not “place” those products “in a distinct market”). And Plaintiff also alleges that the FTC “recognized ‘ACTH drugs’ as a relevant antitrust market when evaluating [Defendant’s] acquisition of Synacthen.” SAC ¶ 89.a.ii. As the Court noted in the March Order, however, the fact that the FTC required Defendant to grant a license only for the treatment of two specific indications “highlights the flaws in a market definition untethered to drugs that are reasonably interchangeable for a given condition.” March Order at 9 n.3.

Plaintiff’s allegations as to this factor cut both ways.

b. Product’s peculiar characteristics and uses

Plaintiff contends ACTH drugs have a “biological mechanism of action [that] is distinct from other drugs in that they stimulate the adrenal gland to produce cortisol” while “Glucocorticoid drugs . . . do not work through the adrenal gland.” SAC ¶ 89.b.i.; see also id. ¶ 51

(“Acthar’s mechanism of action is slightly different from that of corticosteroids”). Similarly, the only other drug approved to treat infantile spasms, Sabril, “is not a steroid, but is instead in a class of anticonvulsant drugs” that “works by inhibiting the breakdown of a particular neural transmitter.” *Id.* ¶ 49 n.3. Defendant contends “the new allegations regarding the nature of corticotropin and its mechanism of action do not negate the fact that for some indications, noncorticotropin treatments remain available.” Mot. at 8. And as the Court previously held, biological differences alone do not render ACTH drugs a distinct market. March Order at 7 n.2. However, the product’s “peculiar characteristics,” is one of many factors the Court is instructed to consider in determining whether the complaint has alleged a plausible submarket.

Importantly, Plaintiff also alleges ACTH drugs have uses different from other drugs used to treat the same conditions. For example, “Acthar is supposed to be a last-line treatment alternative that may be tried after corticosteroids have failed in the hope that Acthar, through its slightly different mechanism of action, may be effective where similar drugs have not been.” SAC ¶ 51; *see also id.* ¶ 89.d.i. (Acthar is supposed to be prescribed only where “those drugs have either failed to treat their conditions or those drugs are contraindicated for that patient.”); *id.* ¶ 89.d.iii (“Humana limits approved use of Acthar (other than for infantile spasms) under its policies to patients who have ‘contraindications or intolerance to corticosteroids that are not expected to also occur with’ Acthar”). And for infantile spasms, “Sabril may be used in combination with long-acting ACTH drugs, or it may be suitable where long-acting ACTH drugs have been ineffective at controlling infantile spasms or were not well tolerated by the patient.” *Id.* ¶ 49 n.3.² Defendant does not

² Defendant contends that “the fact that ‘Sabril may be used in combination with long-acting ACTH drugs’ (SAC ¶ 49 n.3) creates no fact issue as to whether it is not an alternative but a complementary product, like software is to hardware.” Dkt. 78 (Reply) at 2 n.1 (citing Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* § 565a (4th ed. 2020)). Defendant does not

address these allegations, focusing solely on the fact that long-acting ACTH drugs are FDA approved to treat the same conditions as other drugs.³ But, Plaintiff has adequately alleged that, although ACTH drugs and other drugs can be used to treat the same conditions, they are not interchangeable in that doctors or patients are not choosing between long-acting ACTH drugs and other drugs at any given time. Rather, doctors and patients are only turning to long-acting ACTH drugs when other drugs are not an option. This supports a long-acting ACTH submarket.

c. Unique production facilities

Plaintiff alleges that “Acthar is produced at only one facility in Prince Edward Island, Canada . . . using a complex, biologic process that is difficult to replicate” while “Glucocorticoid drugs are synthesized by manufacturers of chemicals for pharmaceuticals in a variety of facilities throughout the world” that “are not equipped to produce Acthar, nor could they be easily modified in order to do so.” *Id.* ¶ 89.c. This supports a long-acting ACTH submarket.

d. Distinct customers

As discussed above, Plaintiff alleges that “[u]sers of Acthar are distinct from users of other adrenal hormone drugs because” Acthar is only supposed to be prescribed where “those drugs have either failed to treat their conditions or those drugs are contraindicated for that patient.” *Id.* ¶ 89.d.i.; see also id. ¶ 89.d.iii (“Humana limits approved use of Acthar (other than for infantile spasms) under its policies to patients who have ‘contraindications or intolerance to corticosteroids that are not expected to also occur with’ Acthar”). Plaintiff further

explain why this is so. Further, at this stage, Plaintiff need not create a fact issue. All factual allegations are accepted as true.

³ That Defendant glossed over the import of these new allegations is evident by Defendant’s incorrect claim that Plaintiff “attempts to justify the[] exclusion [of other drugs] based *solely* on its allegation that ‘the drugs exhibit a very low degree of cross-price elasticity.’” Reply at 1.

alleges that “Acthar is inappropriately prescribed as a result of bribes paid to doctors . . . for patients for whom corticosteroids are an appropriate medical and economic substitute” and “[a]bsent the illegal bribe, Acthar would not be prescribed for these patients.” *Id.* ¶ 89.d.ii. Defendant contends this allegation “confuses the issue more” because Plaintiffs describe Acthar and corticosteroids as “appropriate medical and economic substitute[s].” Mot. at 7. However, the Court understands Plaintiff’s allegation to acknowledge that Acthar is considered for the same type of consumers (or the same uses) only where doctors are choosing to prescribe Acthar improperly and illegally. Because the parties do not address it, the Court assumes, without deciding, that where a Defendant’s alleged illegal conduct causes products to be treated as substitutes when they otherwise would not be, the products are not treated as substitutes for market definition purposes. Therefore, this supports a long-acting ACTH submarket.

e. Distinct prices and sensitivity to price changes

Plaintiff alleges that “Acthar’s price to Humana in 2019 averaged more than \$65,000 per prescription, more than 650,000% of the average prescription price for a glucocorticoid drug (\$9.79),” *id.* ¶ 89.e.i., and “[t]he price of Acthar has increased repeatedly and substantially while the price of other Glucocorticoid drugs has decreased,” *id.* ¶ 89.f.i.; see also *id.* ¶ 62 (from 2011 to 2019 the price of Acthar increased while the price of Glucocorticoid drugs decreased, but the quantity of Acthar reimbursed by Plaintiff substantially increased, while the quantity of reimbursed Glucocorticoid drugs decreased). If the two drugs were economic substitutes, the increasing price disparity between Acthar and Glucocorticoid drugs would have caused consumers to switch from Acthar to Glucocorticoid drugs, but that was not the case. This was confirmed through Plaintiff’s economic analysis of the cross-price elasticity of demand provided in the SAC. *Id.* ¶¶ 63-64.

Defendant challenges Plaintiff's analysis on a number of grounds.⁴ However, these criticisms appear better directed to a challenge at the summary judgment stage based on the parties' expert opinions. For example, Defendant contends the cross-elasticity number is unhelpful because it aggregates indications and excludes non-glucocorticoid alternatives "making it impossible from the allegations to discern whether a positive cross-elasticity of demand exists between ACTH and non-ACTH drugs when used to treat some conditions while a negative cross-elasticity of demand exists when used to treat others." Mot. at 9. Defendant contends the SAC itself "suggest[s] Acthar faces different levels of competition between indications – from glucocorticoids for some indications and from non-glucocorticoid alternatives for others." *Id.* However, beyond infantile spasms, for which glucocorticoids are not FDA approved, the SAC gives no reason to assume that cross-elasticity of demand would be positive for some indications and negative for others. And Plaintiff does not allege that non-glucocorticoid alternatives exist for indications other than infantile spasms. *See* Opp'n at 7 ("Humana believes that no such [non-glucocorticoid alternatives] exist, so it cannot be expected to have identified them itself").

As to infantile spasms, Plaintiff did not perform a cross-elasticity analysis with Sabril. Defendant contends Plaintiff's "argument that Sabril is irrelevant because the [infantile spasm] market is small, and not because of any low cross elasticity of demand (Opp. 8, n.11), is telling." Reply at 2 n.1. However, Defendant points to no requirement that at the motion to dismiss stage, a Plaintiff must perform a statistical econometric analysis of the cross-elasticity of every potential substitute. Plaintiff has alleged that Sabril's characteristics and uses are materially different; that is sufficient at this stage.

⁴ Defendant contends the March Order rejected the factual premise that Defendant was able to raise its price without losing sales. Reply at 1 (citing March Order at 11). But all the Court held was that none of the allegations in the FAC supported that claim. Plaintiff has now added such allegations.

Defendant also contends that because the analysis begins in 2011, it does not exclude any “continuing loss of sales to corticosteroids resulting from the 2007 price adjustment for Acthar and related formulary restrictions” and it also “ignor[es] myriad factors affecting supply and demand for conditions for which Acthar is not commonly used.” Reply at 2. Plaintiff need not exclude all potentially relevant or confounding factors in the rough cross-elasticity analysis set forth in its complaint. Plaintiff’s proposed submarket need only be plausible; it need not be proven.

Finally, Defendant contends Plaintiff’s analysis is flawed because it relies only on its own data. Mot. at 9 n.3. However, Plaintiff covers millions of patients and therefore – particularly at the motion to dismiss stage – its own data can serve as a proxy for the “aggregate demand of consumers.” Id.

Therefore, this factor supports a long-acting ACTH submarket.

f. Specialized vendors

Plaintiff alleges “Acthar is distributed only through a limited network of specialty pharmacies . . . , while other adrenal hormone drugs are widely available through tens of thousands of retail and other mainstream pharmacies throughout the country (e.g. CVS, Rite Aid, Walgreens)” because “Acthar requires special handling that retail pharmacies are not well equipped to provide.” SAC ¶ 83.g.i. This supports a long-acting ACTH submarket

Based on the Brown Shoe factors, the Court concludes Plaintiff has adequately pled a submarket for long-acting ACTH drugs.⁵

2. Antitrust Injury

Plaintiff alleges it was harmed by Defendant’s unlawful conduct because it otherwise “would have paid for fewer Acthar prescriptions and it would have paid less for those prescriptions” because “increased

⁵ The Court therefore need not, and does not, address Plaintiff’s additional allegations in support of direct proof of market power.

competition [from Synacthen] in the market for long-acting ACTH drugs” would have resulted in “lower prices for Acthar” or more prescriptions for the “lower priced Synacthen.” SAC ¶ 137. Defendant contends this presumption depends on a speculative chain of events that if Defendant had not purchased the Synacthen rights, another company “would have secured FDA approval . . . , entered the relevant antitrust market, and gained acceptance among doctors, thereby causing a reduction in the prices that [Plaintiff] paid for Acthar.” Mot. at 10.

Plaintiff argues the allegations in the SAC “are beyond sufficient to make it *plausible* that Synacthen would have been sold in the United States but for Mallinckrodt’s conduct.” Opp’n at 9-10. Specifically, Plaintiff has alleged that Synacthen has been used safely and effectively outside the United States and therefore “a buyer would not need to begin the research, development, testing, or manufacturing process from scratch,” SAC ¶ 70, 75, that Defendant used Synacthen studies to obtain FDA approval for Acthar, *id.* ¶ 71, that the FDA has approved a short-acting formulation of Synacthen, *id.* ¶ 75 n.7, and that there were three other bidders seeking the rights to pursue FDA approval for Synacthen and commercialize it in the United States that had the necessary expertise and financing, as well as sufficient business and regulatory plans, to do so, *id.* ¶¶ 73-74. The Court agrees this is more than sufficient. See Bubar v. Ampco Foods, Inc., 752 F.2d 445, 452 (9th Cir. 1985) (courts consider “[t]he background and experience of [the potential entrant] in his prospective business,” “[a]ffirmative action on the part of [a potential entrant] to engage in the proposed business,” “ability of [a potential entrant] to finance the business and the purchase of equipment and facilities necessary to engage in the business,” and “consummation of contracts” by a potential entrant).

Defendant raises a number of reasons why it believes these allegations are insufficient, none of which the Court finds persuasive. First, Defendant contends that “[c]ourts addressing this issue have required a plaintiff to plead facts establishing the probability and timing of FDA approval for an unapproved drug to be considered a

potential competitor.” Mot. at 12 (citing Andrx Pharm., Inc. v. Biovail Corp. Int’l, 256 F.3d 799, 807-08, 815 (D.C. Cir. 2001) and Brotech Corp. v. White Eagle Int’l Techs. Grp., Inc., No. CIV.A.03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004)). This presumably stems from the requirement that to establish causation in a competitor exclusion case, the plaintiff must allege that the potential competitor has an “intent to enter the market and a preparedness to do so.” See Bubar, 752 F.2d at 450.⁶ Under Defendant’s view, the probability and timing of FDA approval are necessary to make plausible allegations that a competitor is prepared to enter the market. However, particularly where the plaintiff is a consumer rather than a competitor, and where, as here, the defendant is currently in possession of the “asset package,” it would be too exacting a burden to require a plaintiff to allege exactly how long it would take for some other company to get FDA approval. Plaintiff’s allegations make it sufficiently plausible that, but for Defendant’s purchase of the Synacthen rights, Synacthen would have been approved by the FDA for use in the United States for at least one of the same indications as Acthar. That in Brotech the plaintiff had failed to allege when FDA approval “may be anticipated,” 2004 WL 1427136, at *6, and in Tawfilis v. Allergan, Inc., 157 F. Supp. 3d 853

⁶ Plaintiff asserts the cases cited by Defendant address antitrust cases brought by competitors and not consumers, for which there are different burdens. Opp’n at 10-11. However, the circuit courts to have considered the issue have concluded that both consumers and competitors must satisfy the intent and preparedness test. See, e.g., Meijer, Inc. v. Biovail Corp., 533 F.3d 857, 862 (D.C. Cir. 2008) (“Just as a would-be entrant suing an incumbent firm for excluding it from a relevant market in violation of the Sherman Act must demonstrate it intended and was prepared to enter that market, . . . so a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply it but for the incumbent firm’s exclusionary conduct” (internal citations omitted)); Sunbeam Television Corp. v. Nielsen Media Research, Inc., 711 F.3d 1264, 1273 (11th Cir. 2013) (following Meijer and rejecting position that “proof of a ‘willing and able’ competitor ‘standing in the wings, ready to swoop in’ should only apply to *competitor* plaintiffs, not *customer* plaintiffs.”).

(C.D. Cal. 2015), the plaintiff had alleged that approval “could have” occurred within two years, *id.* at 857, does not impose a requirement on all plaintiffs to allege the number of years in which approval is likely to occur. In each of those cases, the court considered the totality of the allegations and concluded that antitrust injury either was or was not plausible. Most of the other cases cited by Defendant were decided at the summary judgment stage and are therefore inapplicable here.

Next, Defendant contends that although it has been three years since it was required to sublicense the rights to Synacthen for infantile spasms and nephrotic syndrome to another company, *id.* ¶ 82, the complaint contains no allegations that Synacthen has obtained FDA approval, or even that the sublicensee has made progress in obtaining FDA approval. Mot. at 13. According to Defendant, this makes it implausible that Synacthen would have been approved by the FDA if another bidder had purchased it in 2013. However, a potential entrant that has the rights to develop and sell Synacthen for only two indications is not similarly situated to a potential entrant that can develop and sell Synacthen for any indication. This is particularly true here where Plaintiff has alleged that the indications for which Defendant retained rights are the cash cows. *See, e.g.*, SAC ¶ 114 (“[F]ewer than 10% of Acthar’s sales come from prescriptions for infantile spasms, and more than 98% of Humana’s expenditures for Acthar were made for insureds over the age of 18”). Therefore, this does not make Plaintiff’s allegations implausible.

Defendant also contends that because Synacthen is a synthetic drug, it “cannot be presumed to have identical effects on the human body” and therefore would be approved by the FDA for the same 19 indications. Mot. at 11; *see also id.* at 13 (“Humana makes no specific allegations regarding Synacthen’s use and effectiveness as to any particular Acthar indication, let alone its relative safety and effectiveness versus Acthar as to such indications”). However, that Defendant used Synacthen studies when it applied for FDA approval and that Synacthen is used for the same indications outside of the United States makes it plausible that Synacthen would be approved for those indications in the United States. Therefore, the Court need not

simply “guess as to whether . . . Synacthen is a plausible replacement for Acthar as the standard of care for [infantile spasms] in the United States, and whether, for other indications, it would be one of several alternatives for ‘first line’ treatment or an alternative to Acthar as a ‘last line’ treatment.” Reply at 5. Moreover, the Court agrees with Plaintiff that it “has suffered antitrust injury if it is plausible that a finder of fact could conclude that Synacthen would have been approved for any use, as the introduction of competition would lower the price of all ACTH drugs.” Opp’n at 10 n.12. There are no allegations that the price of Acthar differs depending on the indication. Therefore, competition for less than all 19 indications could plausibly lower the price for all indications.

Finally, Defendant argues that Plaintiff has not plausibly alleged that the beginning of the alleged antitrust period should be 2011. See Mot. at 13. The bidding process for the rights to sell Synacthen in the United States did not begin until late 2012 and early 2013, and Defendant did not win the rights until June 11, 2013. SAC ¶¶ 76-77. Plaintiff fails to explain how any harm caused by Defendant’s alleged anticompetitive behavior could have occurred prior to Defendant acquiring the Synacthen license. However, the date another bidder could have or would have brought Synacthen to market is a factual question not best resolved at the motion to dismiss stage. Moreover, discovery might reveal that, had it not won the bid, Defendant would have started lowering its prices prior to Synacthen’s market entrance in anticipation of future competition.

The Court concludes Plaintiff has adequately alleged an antitrust injury.

3. Statute of Limitations

Defendant contends that 22 of the 25 state laws relevant to Plaintiff’s state antitrust claims are barred by the statute of limitations because “[a] cause of action for an allegedly anticompetitive acquisition of assets accrues on the date of the acquisition,” which in this case was June 11, 2013, and that statute of limitations for those 22 states is four

years or less. Mot. at 14.⁷ Plaintiff contends its claims were tolled due to fraudulent concealment, the continuing violation doctrine, and American Pipe tolling. Opp’n at 14-19.

a. Fraudulent Concealment

Plaintiff alleges it “could not have discovered and remained unaware” of Defendant’s illegal conduct until the FTC brought these actions to light in 2017 because Defendant “falsely maintained that it would develop and seek FDA approval of Synacthen.” SAC ¶¶ 131-132. For example, Defendant’s chief scientific officer made public statements that Defendant intended to seek FDA approval for Synacthen in conditions different than Acthar and where Synacthen would “potentially provide a clinical benefit over Acthar.” Dkt. 70-2 (RJN Ex. B) (June 2013 Press Release).⁸ However, Plaintiff’s Section 2 claim explicitly alleges that Defendant’s purchase of the license itself, not its failure to commercialize the drug, is the anticompetitive behavior. See SAC ¶ 141 (Section 2 claim alleges that “[b]y intervening in the bidding process for Synacthen and purchasing the exclusive license to market Synacthen in the United States, Mallinckrodt eliminated the potential competitive threat posed by an independently owned Synacthen license”). In other words, as alleged, the “potential competitive threat” was an “independently owned Synacthen license.” Plaintiff should have been aware that there would be no independently owned

⁷ Plaintiff agrees that these 22 states have limitations periods of four or fewer years for antitrust claims, but contends that for two of those states, New York and Oregon, the antitrust claim was statutorily tolled “for one year after the conclusion of any proceeding instituted by the United States under federal antitrust laws.” Opp’n at 19. Defendant appears to concede that these are not time-barred. See Reply at 6 n.3. Therefore, the parties agree that 20 of 25 states relevant to Plaintiff’s state antitrust claim are subject to a statute of limitations defense.

⁸ The Court grants Plaintiff’s unopposed request for judicial notice (Dkt. 70) of a press release issued by Defendant in June 2013. Fed. R. Evid. 201(b).

Synacthen license at the time Defendant publicly announced it would be obtaining the license.

Plaintiff's other allegations provide further support for this conclusion. For example, Plaintiff alleged that "given the drugs' similarities, any therapeutic indication that [Defendant] might have pursued with Synacthen could have been pursued with Acthar." Id. ¶ 79. Plaintiff also alleged that "Novartis was not naïve, and could be expected to understand that Questcor would have little interest in developing the only synthetic competitor to Acthar, its extraordinary lucrative non-synthetic product." Id. ¶ 78. Plaintiff does not explain why it could not have been expected to understand the same thing. Accepting as true the allegation that Defendant falsely stated that it would obtain FDA approval of Synacthen for certain treatments, there are no allegations in the complaint that would support the necessary assumption that had Defendant developed, obtained FDA approval for, and sold Synacthen in the United States, Plaintiff could have reasonably expected to have either paid lower prices for Acthar or that Synacthen would have been offered by Defendant at a materially lower price. Given that Defendant would still control 100% of the alleged product market, whether through one drug or two, the Court cannot plausibly draw the inference that Plaintiff was reasonable in assuming Defendant would have acted to its financial detriment and lowered the price of Acthar or introduced Synacthen at a substantially lower price. See Iqbal, 556 U.S. at 679 (Courts must "draw on their judicial experience and common sense" in determining whether allegations in a complaint are plausible). Fraudulent concealment, therefore, does not save Plaintiff's otherwise time-barred claims.⁹

⁹ Plaintiff's footnote implicitly arguing that the Court should find fraudulent concealment here because of the Court's conclusion as to Plaintiff's RICO claim, Opp'n at 15 n.20 (citing March Order at 25), is misplaced. The facts necessary to put Plaintiff on inquiry notice of the RICO claims differs materially from the types of facts that would put Plaintiff on inquiry notice of the antitrust claims.

b. Continuing Violation

Plaintiff also contends that Defendant's actions constitute a continuing violation because "its yearly licensing payments to Novartis have forestalled and continue to forestall the transfer of Synacthen rights to a party that would develop it to compete with Acthar." Mot. at 18.¹⁰ Specifically, Defendant pays Novartis \$25 million each year to maintain its monopoly in the long-acting ACTH market and Plaintiff contends that "[e]ach payment is anticompetitive in that it forestalls Novartis from licensing its drug to others and enables Mallinckrodt to charge monopoly prices." Id. Essentially, each payment is a new contract preventing Synacthen from being developed to compete with Acthar. The Court agrees.

"To state a continuing violation of the antitrust laws in the Ninth Circuit, a plaintiff must allege that a defendant completed an overt act during the limitations period that meets two criteria: '1) It must be a new and independent act that is not merely a reaffirmation of a previous act; and 2) it must inflict new and accumulating injury on the plaintiff.'" Samsung Elecs. Co. v. Panasonic Corp., 747 F.3d 1199, 1202 (9th Cir. 2014) (quoting Pace Indus., Inc. v. Three Phoenix Co., 813 F.2d 234, 238 (9th Cir. 1987)). Cases where "all of the harm occurred at the time of the initial violation . . . is the exception, not the rule. Id. at 1202-03. Instead, "[n]on-legal actions taken pursuant to a pre-limitations period contract can lead a new cause of action to accrue." Id. at 1203.

Defendant first contends the continuing violation theory does not apply because "[u]nilateral decisions about whether to develop a new product . . . are *not* subject to antitrust scrutiny." Reply at 6. However, Plaintiff is not claiming anticompetitive conduct simply because Defendant chose not to develop an Acthar competitor. The anticompetitive conduct stems from Defendant's decision to prevent

¹⁰ The Court grants Plaintiff's unopposed request for judicial notice (Dkt. 70) of Defendant's SEC filings and the license agreement with Novartis (Dkts. 70-1, 70-3 through 70-8). Fed. R. Evid. 201(b).

others from developing an Acthar competitor by continuing to pay Novartis for the Synacthen license. Therefore, the Court finds this argument unconvincing.

Next, Defendant contends the continuing violation theory does not apply because “the license agreement [does not] contain[] a provision requiring [Defendant] to ‘shelve’ Synacthen.” Reply at 7. However, Defendant cites no case law imposing a requirement for the agreement to explicitly compel the anticompetitive conduct. Moreover, the license agreement itself explicitly prevents companies other than Defendant from developing Synacthen for sale in the United States, thereby proscribing any independently owned Synacthen license, the anticompetitive conduct at issue here. And “action taken under a pre-limitations contract [i]s sufficient to restart the statute of limitations so long as the defendant had the ability not to take the challenged action, even if that would have required breaching the allegedly anti-competitive contract.” Samsung, 747 F.3d at 1203.

Finally, Defendant contends recent cases have held that the continuing violation theory does not apply to antitrust allegations based on price increases after an acquisition. Reply at 7-8 (citing Midwestern Mach., Inc. v. Nw. Airlines, Inc., 167 F.3d 439, 440 (8th Cir. 1999) and Z Techs. Corp. v. Lubrizol Corp., 753 F.3d 594, 603 (6th Cir. 2014)). These cases are factually distinct from the alleged antitrust violations at issue here, which involve more than an incidental price increase ultimately caused by an acquisition. Here, the antitrust conduct is the continuing payments to Novartis to prevent another company from developing an Acthar competitor. A similar arrangement was found to be a continuing violation by the Ninth Circuit in Samsung. 747 F.3d at 1204 (because “the license itself did not permanently and finally control the acts of the SD Defendants[,] [t]heir decision to enforce the contract caused a new anti-competitive harm, and the statute of limitations ran anew from the time that defendants began enforcement.”). To the extent the cases cited by Defendant contradict Ninth Circuit law as set forth in Samsung, the Court disregards them.

Therefore, the statute of limitations does not bar Plaintiff from asserting claims based on harms flowing from the alleged anticompetitive license payments made to Novartis during the limitations period.

c. American Pipe Tolling

Plaintiff contends it is also “entitled to tolling of its claims under *American Pipe* as of [April and October of 2017 when class actions were filed against Defendant], because in those cases [Plaintiff] is a putative member of the classes and its antitrust claims share a common factual and legal basis with the claims asserted.” Opp’n at 15 n.21. Defendant notes that only the April 2017 lawsuit would fall within the statute of limitations, but Plaintiff was not included in the proposed class until an amended complaint was filed in December 2017, after the expiration of the four-year limitations period. See Reply at 8. Therefore, American Pipe does not save Plaintiff’s state law claims to the extent based on the 2013 license agreement.¹¹

Defendant’s motion to dismiss the First and Second Counts is DENIED. Defendant’s motion to dismiss the Third Count is DENIED as to claims brought under New York, Oregon, Maine, Vermont, and Wisconsin law. As to the remaining state law antitrust claims, Defendant’s motion is GRANTED to the extent Plaintiff seeks to challenge the 2013 license agreement (and any other conduct outside of the relevant limitations period), but DENIED as to Defendant’s alleged continuing antitrust violations within the limitations period.

¹¹ It does not appear that Defendant disputes that the complaints filed on October 30, 2017 and December 8, 2017 would toll the statute of limitations for claims based on conduct that occurred within four years of those dates.

B. RICO (Counts IV and V)

The Court previously held that Plaintiff had adequately alleged RICO claims based on an alleged “Acthar Enterprise,” consisting of Defendant, CDF, and the prescribing doctors, that participated in a pattern of racketeering activity including 1) mail and wire fraud based on Defendant’s and prescribing doctors’ misrepresentations that they were complying with state and federal law, when in fact a) the co-pay assistance programs violated the Anti-Kickback Statute (AKS) and the False Claims Act (FCA), and b) the doctor payments violated state bribery laws and 2) bribery based on the doctor payments. March Order 13-34.¹² In so deciding, the Court rejected Defendant’s contention that any racketeering acts related to the co-pay assistance funds occurred outside the four-year statute of limitations. *Id.* at 23-25.

Defendant now contends that the Court’s “reasoning [on the statute of limitations issue] invites consideration of judicially noticeable facts establishing that the claim is time-barred.” Mot. at 3.¹³ Defendant identifies a 2013 New York Times article that purportedly establishes that Humana “would have been on notice of its alleged claim” more than four-years before it filed this action. Id. at 4; see also id. at 18 (“the alleged conduct has been public knowledge since 2013”), id. at 19 (“major news media reported – as early as 2013 – about Questcor’s alleged contributions to the CDF funds at issue and their purported Acthar-only nature”). However, Defendant does not explain

¹² The Court also held that Plaintiff had not adequately alleged any racketeering activity based on alleged insured misrepresentations or the theory that co-pay assistance was bribery. March Order at 26-28. The Court invited Plaintiff to amend those claims to the extent it wished to continue pursuing them. *Id.* at 35 n.21. Because Plaintiff chose not to amend those claims, it has abandoned them. For the sake of clarity, the Fourth and Fifth Counts, to the extent they rely on either of these theories, are DISMISSED.

¹³ Defendant concedes it is not entitled to dismissal based on the allegations in the SAC alone. See Mot. at 19 (Defendant “agrees that [Plaintiff] had not pled admissions on the critical issue of what it knew about the CDF funds at the time”).

how the Court's reasoning in the March Order warrants reconsideration of the statute of limitations issue. The Central District of California permits only three grounds on which a motion for reconsideration may be made:

- (a) a material difference in fact or law from that presented to the Court before such decision that in the exercise of reasonable diligence could not have been known to the party moving for reconsideration at the time of such decision, or
- (b) the emergence of new material facts or a change of law occurring after the time of such decision, or
- (c) a manifest showing of a failure to consider material facts presented to the Court before such decision.

Local Rule 7-18. The new article is at best a material difference in fact, but Defendant makes no argument that it could not have discovered the article in the exercise of reasonable diligence prior to the March Order. Therefore, the Court declines to reconsider its prior determination that Plaintiff had adequately alleged it discovered Defendant's wrongdoing within the limitations period.

Further, as Plaintiff points out, even if the Court were to consider the article, it would not change the outcome. One or two articles are insufficient to show, as a matter of law, that Plaintiff had constructive notice of the facts contained within them.¹⁴ Additionally, the Court previously concluded that because Plaintiff alleged that the donation agreements fraudulently misrepresented that the funds were not limited to patients using Acthar, had Plaintiff inquired into the funds,

¹⁴ Defendant contends that its argument is not that the articles themselves should have put Plaintiff on notice, but that the OIG's 2014 SAB, which purportedly singled out the emergence of single-drug funds, should have caused Plaintiff to run some Google searches to see if there were any articles about drugs covered by Plaintiff. Reply at 11. Whether Plaintiff's investigation (or lack thereof) in response to the 2014 SAB was reasonable is a factual issue not best resolved at the motion to dismiss stage.

it would not have discovered that the funds were illegal. March Order at 24-25.

Defendant's motion to dismiss Counts Four and Five to the extent based on allegations regarding co-pay assistance programs is DENIED.

C. State Law Claims (Counts VI through X)

1. Statute of Limitations

Defendant contends that 21 of the 25 states' laws under which Plaintiff brings its unfair competition and consumer fraud and deceptive trade practices claims, as well as four of the five states' laws under which Plaintiff brought an insurance fraud claim are also barred by the relevant statutes of limitations to the extent they are based on the co-pay assistance funds. Mot. at 20. The Court declines to dismiss those claims for the same reason stated in section III.B. and for the additional reason that Defendant did not raise this contention in its prior motion and therefore is prohibited from doing so here under Rule 12(g)(2). See In re Apple iPhone Antitrust Litig., 846 F.3d 313, 317-318 (9th Cir. 2017), aff'd sub nom. Apple Inc. v. Pepper, 139 S. Ct. 1514 (2019) ("a defendant who fails to assert a failure-to-state-a-claim defense in a pre-answer Rule 12 motion cannot assert that defense in a later pre-answer motion under Rule 12(b)(6)").

2. Individual Defenses to State Laws

Defendant next contends Plaintiff's claims under Kentucky and New Jersey insurance fraud statutes also fail because the Kentucky statute requires a criminal adjudication of guilt and the New Jersey statute requires "prelitigation notice . . . with which [Plaintiff] has not alleged compliance." Mot. at 15 n.8. Not only does Rule 12(g)(2) prevent Defendant from making these arguments in a successive pre-answer motion to dismiss, but it is also legally incorrect. As Plaintiff notes, the Kentucky legislature repealed the requirement of criminal adjudication. See 2018 Kentucky Laws Ch. 178 (HB 323) (removing requirement of a "criminal adjudication of guilt" for a private party to

state a claim for damages). And as to the New Jersey statute, prelitigation notice is not required. See N.J. Stat. § 17:33A-7(c) (notice to be provided at the time of filing). In reply, Defendant appears to concede that Plaintiff can assert its claim under New Jersey law. Reply at 12 (“Mallinckrodt requests that the Court dismiss with prejudice . . . all other claims (except that under New Jersey’s Insurance Fraud Statute)”).

Defendant attaches to its brief “Appendix B,” a chart of legal defenses to Plaintiff’s unfair competition and consumer fraud and deceptive trade practices claims. See Mot. at 23-25. That chart includes the following arguments:

- Michigan’s statutes do not apply to regulated activities, such as the provision of prescription drugs to Medicare beneficiaries, or alleged misrepresentations not made to customers
- Minnesota’s statutes require claims to satisfy the public benefit requirement and therefore do not apply to claims for recovery of private damages
- New Jersey’s statutes do not permit claims brought by third-party payors, rather than drug consumers
- North Dakota’s statutes do not apply to statements made in connection with coverage, rather than in connection with the sale or advertisement of a drug

Although technically within the 25-page limit, Appendix B skirts the purpose of the page limitation by including additional argument in size 11 font, single-spaced. Moreover, the arguments were not raised in the prior motion and are therefore improper under Rule 12(g)(2). The Court will not consider these additional defenses at this time.

3. Tortious Interference

The Court previously dismissed Plaintiff’s tortious interference claim because Plaintiff had failed to allege that accepting co-pay

assistance caused its members to breach their contract with Plaintiff. March Order at 34. Plaintiff has added allegations that its contracts with its members “provide[] that an insured is ‘responsible for’ copayments and ‘must pay [their] share of the cost when [they] get [a] service or drug.’” SAC ¶ 202. The contract also states that “when you get a drug through a patient assistance program offered by a drug manufacturer . . . we will not pay for any share of these drug costs.” Id. Plaintiff contends that “[i]f the [patient assistance program] uses its funds to pay the member’s co-pay, however, then both the letter and the purpose of the [contract] provision are subverted.” Id. ¶ 203.

But nothing in the cited provisions can reasonably be read as preventing members from paying their co-pays with money obtained from a co-pay assistance fund. The first provision, as discussed in the March Order, merely requires members to pay their co-pays. It sets no limitations on the source of the funds. The second provision, when read in context, does not prohibit members from doing anything it all. It is only a reminder that if members obtain drugs outside of their plan benefits directly from the drug manufacturer through a patient assistance program, Plaintiff will not reimburse members for any payments made to the patient assistance programs. Here, in contrast, the members do obtain the drugs through their insurance, and simply obtain the funds to pay the co-pays through a co-pay assistance fund. That is not prohibited by the contracts. The contract does not say that if a co-pay assistance fund covers the co-pay, Plaintiff was entitled to deny coverage in the first place, when it otherwise would have provided coverage. Moreover, there is simply nothing in the cited provision that requires members to “identif[y]” whether co-pay assistance “originat[ed] with the manufacturer.” Id. Therefore, it does not follow that “it is a breach for the member to use that assistance to procure payment for the manufacturer’s drug.” Id.; see also id. (“Mallinckrodt is causing Humana members to procure a benefit under the contract to

which the members are not entitled under the contract's plain terms.")¹⁵

Therefore, Plaintiff has still not alleged that its members breached their contracts, and the Court determines that Plaintiff cannot plead any other facts that would cure this deficiency. See Schreiber, 806 F.2d at 1401 (leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency"). Count IX is DISMISSED with prejudice.

IV. CONCLUSION

Count III, to the extent it relies on laws from states other than New York, Oregon, Maine, Vermont, and Wisconsin and relies on the 2013 license agreement, Counts IV and V, to the extent they rely on purported racketeering activity based on alleged insured

¹⁵ In half a sentence Plaintiff contends that members' acceptance of co-pay assistance is alternatively "disruption' of the contractual relationship." Opp'n at 21 (citing Redfearn v. Trader Joe's Co., 230 Cal. Rptr. 3d 98, 104 (2018)). This is insufficient to preserve this argument. See Birdsong v. Apple, Inc., 590 F.3d 955, 959 (9th Cir. 2009) ("[A] bare assertion does not preserve a claim, particularly when, as here, a host of other issues are presented for review."); see also Indep. Towers of Washington v. Washington, 350 F.3d 925, 929-30 (9th Cir. 2003) ("However much we may importune lawyers to be brief and to get to the point, we have never suggested that they skip the substance of their argument in order to do so. . . . We require contentions to be accompanied by reasons."); Mahaffey v. Ramos, 588 F.3d 1142, 1146 (7th Cir. 2009) ("Perfunctory, undeveloped arguments without discussion or citation to pertinent legal authority are waived").

misrepresentations or the theory that co-pay assistance was bribery, and Count IX are DISMISSED with prejudice. Defendant's motion is otherwise DENIED.

IT IS SO ORDERED.

Date: August 14, 2020



Dale S. Fischer
United States District Judge

EXHIBIT 53

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

Hon. Stephen Kaus

PROOF OF SERVICE

PROOF OF SERVICE

I, Kelle J. Winter, declare the following:

I am over the age of eighteen years and not a party to the within entitled action. I am employed at Schneider Wallace Cottrell Konecky LLP located at 2000 Powell Street, Suite 1400, Emeryville, CA 94608.

On **August 17, 2020**, I served the following document(s) described as:

• **NOTICE OF SUPPLEMENTAL AUTHORITY**

on the following interested party(s):

D. Eric Shapland
ARNOLD & PORTER KAYE SCHOLER LLP
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eric.shapland@arnoldporter.com

☒ **BY ELECTRONIC SERVICE** by electronically mailing a true and correct copy in PDF format through SWCKW's electronic mail system to the email address(s) set forth above.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on August 17, 2020, at Scottsdale, Arizona.

/s/ Kelle J. Winter
Kelle J. Winter

EXHIBIT 54

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24 SUPERIOR COURT OF THE STATE OF CALIFORNIA

25 COUNTY OF ALAMEDA

26 HEALTH CARE SERVICE CORP.,

27 Plaintiff,

28 v.

29 MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
30 ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
31 MALLINCKRODT plc,

32 Defendants.

Case No. RG20056354

**THE DEFENDANT
MALLINCKRODT ENTITIES'
NOTICE OF SUPPLEMENTAL
AUTHORITY RE DEMURRER AND
MOTION TO STRIKE**

Date: August 19, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Res. Nos. 2179414 & 2179416

Action Filed: February 27, 2020

ENDORSED
FILED
ALAMEDA COUNTY

AUG 18 2020

CLERK OF THE SUPERIOR COURT

Anita Dhir

Defendant Mallinckrodt ARD LLC (“Mallinckrodt”) submits this notice of supplemental authority (a) to response to Plaintiff Health Care Service Corp. (“HCSC”)’s notice of supplemental authority re an order on Mallinckrodt’s second motion to dismiss in *Humana Inc. v. Mallinckrodt ARD LLC*, C.D. Cal. No. 19-cv-06923 (August 14, 2020), and (b) to notify the Court of an order today on Mallinckrodt’s motion to dismiss in another related case: *United Association of Plumbers & Pipefitters Local 322*, D.N.J. (Aug. 18. 2020). The latter slip opinion is attached hereto as Exhibit A.

Response to HCSC’s Notice re *Humana*

As HCSC has informed this Court, Judge Dale S. Fischer of the United States District Court for the Central District of California issued a ruling last Friday on a motion to dismiss in the related case *Humana Inc. v. Mallinckrodt ARD LLC*, C.D. Cal. No. 19-cv-06923. Far from a neutral notice of supplemental authority, HCSC’s submission is a selective advocacy piece that warrants this short response. Contrary to HCSC’s contention (“Notice at 3:7-10), Judge Fischer’s decision does not support HCSC’s contention that the Mallinckrodt defendant’s demurrer and motion to strike in this case are procedurally improper and should be denied in their entirety.

First, Humana did not even include in its complaint two categories of alleged misconduct that HCSC pleads, but failed to meaningfully defend: (a) the shift to an exclusive distributor of Acthar for specialty pharmacies, which HCSC admits is not unlawful in itself, and (b) the allegation of supposed off-label promotion of Acthar that HCSC does not allege was ever communicated to HCSC and HCSC could not describe with *any* specificity let alone with the particularity required to plead fraud. Because Humana did not include those flawed allegations in its complaint, Judge Fisher did not need to address them. Mallinckrodt urges this Court to eliminate those categories of alleged misconduct and related claims from this case.

Second, Judge Fischer granted Mallinckrodt’s motion to dismiss in part and denied in it in part. Judge Fischer dismissed with prejudice Humana’s tortious interference claim, which is identical to HCSC’s Count VIII. Notice Ex. A at 26-28. She also dismissed Humana’s antitrust claims under California and other states’ antitrust laws (other than those of New York, Oregon, Maine, Vermont, and Wisconsin law) under the applicable four-year statutes of limitations, to the

1 extent the claims challenge a seven-year old acquisition by Mallinckrodt's predecessor of rights to
 2 Synacthen. *Id.* at 17-22. HCSC brings identical claims. While HCSC attempts to distinguish its
 3 claims from Humana's, it does so by pointing to its challenge to Mallinckrodt's exclusive
 4 distribution of Acthar to specialty pharmacies, which, again, fails to state a claim or support any
 5 form of antitrust claim.

6 *Third*, while Judge Fischer's decision from last Friday, like her decision granting in part and
 7 denying in part Mallinckrodt's prior motion to dismiss in *Humana*, serves as persuasive authority
 8 for this Court in considering Mallinckrodt's pending demurrer and motion to strike, Mallinckrodt
 9 urges this Court to consider the full context of those decisions and to exercise its own independent
 10 judgment with respect to the merits of HCSC's claims. In her ruling on Mallinckrodt's first motion
 11 to dismiss in *Humana*, Judge Fischer dismissed Humana's antitrust claims as framed in the
 12 complaint that HCSC copied to bring this action. She also rejected HCSC's theory here that copay
 13 assistance constitutes a violation of state commercial bribery statutes and thus a predicate act under
 14 RICO and other fraud theories. That allegation should be stricken from HCSC's complaint.
 15 Moreover, in Friday's ruling, she permitted a portion of Humana's state law challenges to the seven-
 16 year-old Synacthen acquisition to proceed, notwithstanding the applicable four-year limitations
 17 period, under an application of the continuing violation doctrine that Mallinckrodt has shown to be
 18 erroneous here (Reply at 16-17). And to reject Mallinckrodt's argument that news articles put
 19 Humana on constructive notice of its copay assistance claims, Judge Fischer reasoned *in part* that
 20 Mallinckrodt had not made the news articles part of the record on its first motion to dismiss. Notice
 21 Ex. A. at 23-24. Mallinckrodt made those news articles part of the record on its only demurrer in
 22 this case.

23 In short, Judge Fischer's decisions in *Humana* are a relevant and useful persuasive authority
 24 of this Court to consider in resolving Mallinckrodt's pending motions. They are not the blanket
 25 confirmation of a summary denial of those motions that HCSC suggests.

26 **Notice re Decision in *Plumbers*.**

27 The *Plumbers* case is a related case pending in the United States District Court for the
 28 Northern District of New Jersey. The plaintiff there, like HCSC here, is a third-party payer who

alleges that Mallinckrodt's predecessor in interest engaged in same five categories of misconduct that HCSC alleges here. Mallinckrodt and its co-defendant Express Scripts entities moved to dismiss the plaintiffs' claims and, in support of those motions, made many of the same arguments included in Mallinckrodt's demurrer and motion to strike in this case. As to the areas of overlap between the arguments and claims, the Honorable Robert B. Kugler held as follows:

- (1) The plaintiff's allegations regarding Mallinckrodt's distribution agreement with CuraScript SD and other components of its distribution chain failed to state a claim for relief under the antitrust laws. Op. at 25-31. In doing so, Judge Kugler accepted the arguments that Mallinckrodt makes here regarding the procompetitive nature of those agreements, the lack of any allegations of harm to competition, and the errors of the decision in *Rockford v. Mallinckrodt* on which HCSC relies.
- (2) The plaintiffs' New Jersey RICO and other fraud-based claims failed to state a claim for relief. Op. at 36-37. Judge Kugler reasoned in relevant part that the plaintiff's allegations regarding supposed off-label promotion and bribes to doctors were highly generalized and lacked the particularity required to state a claim for fraud.
- (3) The plaintiff had stated an antitrust claim against Mallinckrodt in relation to the Synacthen acquisition. Op. 23-25, 31-33. In doing so, Judge Kugler rejected Mallinckrodt's argument that Plaintiff's proposed ACTH-only market and allegations of antitrust injury were implausible.

Dated: August. 18, 2020

Respectfully Submitted,
ARNOLD & PORTER KAYE SCHOLER LLP

By: 
 Sonia Kuester Pfaffenroth

*Attorneys for Defendant
 Mallinckrodt ARD LLC and
 Mallinckrodt plc*

EXHIBIT A

NOT FOR PUBLICATION

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

UNITED ASSOCIATION OF
PLUMBERS & PIPEFITTERS LOCAL
322 OF SOUTHERN NEW JERSEY,
*individually and on behalf of all others
similarly situated,*

Plaintiff,

v.

MALLINCKRODT ARD, LLC, *et al.*,

Defendants.

Civil No. 20-188 (RBK/KMW)

OPINION

KUGLER, United States District Judge:

This case concerns allegations of a long running conspiracy to dramatically inflate the price of a venerable drug, H.P. Acthar Gel (“Acthar”). Presently before the Court are a number of motions: Plaintiff United Association of Plumbers & Pipefitters Local 322 of Southern New Jersey’s (“Local 322”) Motion to Transfer Case to the Eastern District of Pennsylvania (Doc. No. 12); Defendants Mallinckrodt ARD, LLC and Mallinckrodt plc’s (collectively, “Mallinckrodt”) Motion to Stay Proceedings (Doc. No. 16); Defendants Accredo Health Group, Inc., Cigna Corporation, CuraScript SD, CuraScript, Inc., Cigna Holding Company, Express Scripts Holding Company, Express Scripts, Inc., Priority Healthcare Corp. and Priority Healthcare Distribution, Inc., and United Biosource Corporation’s (collectively, “Express Scripts”) Motion to Dismiss (Doc. No. 18); Mallinckrodt’s Motion to Dismiss (Doc. No. 19); Defendant Lisa Pratta’s Motion to Dismiss (Doc. No. 25); Mallinckrodt and Express Scripts’ Joint Motion to Strike (Doc. No. 41);

Pratta's Motion to Strike (Doc. No. 43); Mallinckrodt's Motion to Dismiss Plaintiff's Amended Complaint (Doc. No. 49); Express Scripts' Motion to Dismiss Plaintiff's Amended Complaint (Doc. No. 50); and Pratta's Motion to Dismiss Plaintiff's Amended Complaint (Doc. No. 55).

For the reasons set forth below, Plaintiff's Motion to Transfer is **DENIED**; Mallinckrodt's Motion to Stay is **DENIED**; Mallinckrodt, Express Scripts, and Pratta's Motions to Dismiss are **DENIED** as moot; the Motions to Strike are **DENIED**; Mallinckrodt's Motion to Dismiss the Amended Complaint is **GRANTED IN PART** and **DENIED IN PART**; and Express Scripts and Pratta's Motions to Dismiss are **GRANTED**.

I. BACKGROUND¹

A. The Parties

Plaintiff is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. (FAC at ¶ 27). As such, Plaintiff is a "third-party payor" or "TPP" in health care industry parlance. This lawsuit arises from Plaintiff's 2018 payment of \$26,100.28 for one administration of Acthar on behalf of one of its beneficiaries. (*Id.* at ¶¶ 27–29, 239).

Acthar is the only therapeutic adrenocorticotrophic hormone ("ACTH") product sold in the United States. (*Id.* ¶¶ 3, 64). Mallinckrodt ARD, LLC is the sole manufacturer of Acthar in the United States. (*Id.* at ¶ 3). Since August 2014, Mallinckrodt ARD, LLC has been a wholly-owned subsidiary of Mallinckrodt plc. (*Id.* ¶ 31–33). Prior to its acquisition by Mallinckrodt plc, Mallinckrodt ARD, LLC was known as Questcor Pharmaceuticals, Inc. (*Id.* at ¶ 30). For simplicity, throughout this Opinion the Court will refer to this entity as "Mallinckrodt," even when discussing the time period when it was known as Questcor Pharmaceuticals, Inc.

¹ The following facts are drawn from Plaintiff's Amended Complaint (Doc. No. 40 ("FAC")).

Unlike most prescription drugs, Acthar is a “specialty pharmaceutical,” meaning that it is not sold in retail pharmacies, but only distributed through “specialty pharmacy distributors” and “specialty pharmacy providers.” (*Id.* at ¶ 5). CuraScript, Inc. and its affiliates CuraScript SD and Priority Healthcare Corp. and Priority Healthcare Distribution, Inc. (collectively, “CuraScript”) is the specialty pharmacy distributor for Acthar. (*Id.* at ¶¶ 6, 44–46). Accredo Health Group, Inc. (“Accredo”) is the specialty pharmacy provider for Acthar. (*Id.* ¶¶ 6, 49). Accredo reviewed and approved the administration of Acthar that Plaintiff paid for, and CuraScript delivered that administration of Acthar to Plaintiff’s beneficiary. (*Id.* at ¶¶ 48, 51).

CuraScript and Accredo are wholly-owned subsidiaries of Express Scripts, Inc. (*Id.* at ¶¶ 45, 49). As of December 2018, Express Scripts, Inc. is a wholly-owned subsidiary of Cigna Corporation and Cigna Holding Company. (*Id.* at ¶ 42).

United BioSource Corporation (“UBC”) coordinates Acthar sales, distribution, and payment between Mallinckrodt, Express Scripts, patients, physicians, and TPPs. (*Id.* at ¶¶ 52–55). UBC processed the paperwork submitted by Plaintiff to obtain the Acthar dose for its beneficiary. (*Id.* at ¶ 56). Between 2012 and November 2017, UBC was a wholly owned subsidiary of Express Scripts. (*Id.* at ¶ 52). In November 2017, UBC was sold to Avista Capital Partners, a private equity firm; presently, UBC is a wholly owned subsidiary of United BioSource Holdings, Inc., which is held by various entities affiliated with Avista Capital Partners. (*Id.* at ¶ 53).

Lisa Pratta was an Acthar sales representative for Questcor and Mallinckrodt from September 2010 until June 2017. (*Id.* at ¶¶ 59, 401). Pratta was in charge of the South New Jersey region. (*Id.* ¶ 410).

B. Acthar

As an ACTH drug, Acthar causes the body to produce cortisone and other steroid hormones. (FAC at ¶ 64). ACTH triggers the adrenal glands to make cortisol, which is equivalent to the steroid prednisone. (*Id.* at ¶ 66). Consequently, taking ACTH effectively replicates the effects of taking prednisone. (*Id.*). Acthar is known generically as corticotropin. (*Id.* at ¶ 102).

Acthar was developed by the Armour Pharmaceutical Company and in 1952 was initially approved by the Food and Drug Administration (“FDA”) for over fifty indications. (*Id.* at ¶¶ 63–65). However, after an FDA review in the 1970s concluded that many of Acthar’s indications lacked substantial evidence of effectiveness, Acthar was left with only nineteen approved indications. (*Id.* at ¶¶ 109–112). Today, Acthar’s approved indications include the treatment of infantile spasms (“IS”), the acute exacerbations of Multiple Sclerosis (“MS”), and “[a]s adjunctive therapy for short term administrations . . . in the following Rheumatic Disorders: Psoriatic arthritis, Rheumatoid arthritis, including juvenile arthritis . . . [and] Ankylosing spondylitis.” (*Id.* at ¶ 120). Many of these indications can be effectively treated by generic corticosteroids, such as prednisone, which are widely available for little more than \$4 per dose. (*Id.* at ¶¶ 114–15, 122–34).

By contrast, Acthar does not face competition from these generics in the market for treating IS. (*Id.* at ¶ 114). Indeed, Acthar is the “gold standard” treatment for IS. (*Id.* at ¶ 140). However, the IS treatment market is limited, as the condition affects less than 2,000 children per year. (*Id.*).

C. The New Strategy

In 2001, Mallinckrodt acquired Acthar from Aventis Pharmaceutical Products, Inc. for \$100,000. (*Id.* at ¶ 138). At the time of Mallinckrodt’s acquisition, a vial of Acthar sold for \$40. (*Id.* at ¶ 114). Further, Acthar was not approved for treating IS; the FDA would not approve this indication until 2010. (*Id.* at ¶ 140). Nevertheless, between 2001 and 2007, Acthar’s primary sales were for treating IS as an off-label indication. (*Id.* at ¶ 141).

Plaintiff alleges that in 2007, Mallinckrodt launched an “orphan drug strategy” designed to leverage its market power in the IS treatment market. (*Id.* at 174). Under this plan, Mallinckrodt would attempt to make it appear as though Acthar was a new product by “relaunching” it with a limited distribution system and a substantially higher price, emphasizing that it was the only product available for treating IS. (*Id.* at ¶ 174). Plaintiff alleges that this plan had three distinct elements: (1) a “distribution scheme,” by which Mallinckrodt made Express Scripts the sole distributor of Acthar; (2) a “pricing scheme,” by which Mallinckrodt dramatically inflated the price of Acthar; and (3) a “marketing scheme” by which Mallinckrodt and Express Scripts disseminated misleading information about the safety and efficacy of Acthar in order to maintain and even grow demand despite the price increases.

i. The “Distribution Scheme”

Prior to Mallinckrodt’s acquisition, Acthar was distributed to any doctor, hospital, wholesaler, or specialty pharmacy who requested the drug. (*Id.* at ¶ 152). However, on July 2, 2007, Mallinckrodt restricted distribution of Acthar to Express Scripts. (*Id.* at ¶ 153). Specifically, Mallinckrodt entered into an exclusive distribution agreement with CuraScript. (*Id.* at ¶¶ 44–46, 163). Mallinckrodt also entered into an agreement with UBC whereby UBC would coordinate the sale, distribution, and reimbursement for Acthar. (*Id.* at ¶¶ 154, 163).

With the CuraScript and UBC agreements in place, Mallinckrodt implemented a new distribution program known as the “Acthar Support & Access Program” (“ASAP”). (*Id.* at ¶ 180). Under the ASAP, the only way for a patient or physician to obtain Acthar is by completing an Acthar Start Form and faxing it to UBC. (*Id.* at ¶ 184). Upon receipt of this form, UBC confirms the prescription by the provider and the associated specialty pharmacy and confirms the patient’s insurance. (*Id.* at ¶ 185). If everything checks out, UBC arranges for CuraScript to deliver the

Acthar directly to the patient. (*Id.*). UBC also receives payment from the patient and/or their TPP and then distributes payment to Mallinckrodt. (*Id.* at ¶ 189). Mallinckrodt maintains all rights, title, and interest in the Acthar until UBC approves delivery to the patient. (*Id.* at ¶ 191).

ii. The “Pricing Scheme”

Upon its acquisition of Acthar, Mallinckrodt moved quickly to increase the price, and by September 2001 the average wholesale price (“AWP”) was \$935.20. (*Id.* at ¶ 209).² By 2007, the AWP had grown to \$2,062.79. (*Id.* at ¶ 211). After Mallinckrodt implemented the new strategy in August 2007, Acthar’s AWP increased dramatically to \$29,086.25—a 1,310% increase in the span of a month. (*Id.* at ¶ 214). Once Mallinckrodt obtained FDA approval for the IS indication in 2010, it increased the AWP of Acthar again, such that by 2012 the AWP was \$34,150.00. (*Id.* at ¶ 215). Plaintiff alleges that CuraScript and UBC conspired with Mallinckrodt to effectuate at least some of these price increases. (*Id.* at ¶¶ 13, 214).

Further, Plaintiff claims that Mallinckrodt has made misleading or inaccurate statements about its Acthar pricing strategy at various other times. (*Id.* at ¶¶ 550–54). For example, in 2018 Mallinckrodt’s CEO, Mark Trudeau, stated that the AWP of Acthar was only \$36,382, and that Mallinckrodt offers discounts to public and private payers. (*Id.* at ¶ 233).³ Yet by 2018, the AWP of Acthar was over \$40,000, and Plaintiff alleges that Mallinckrodt does not offer any discounts to TPPs. (*Id.* at ¶ 234).

iii. The “Marketing Scheme”

² Like other drug manufacturers, Mallinckrodt set the wholesale acquisition cost (“WAC”) for Acthar and then charged a 25% markup. (*Id.* at ¶ 209). As such, the AWP is 25% above the WAC.

³ According to Plaintiffs, TPPs determine reimbursement payments for prescriptions based on the AWP’s reported by pharmaceutical industry publications. (*Id.* at ¶ 242). Further, Plaintiff alleges that Mallinckrodt was supplying “false” AWP’s to these publications in an effort to manipulate the price actually paid by TPPs. (*Id.* at ¶¶ 242–45). However, Plaintiff also seems to assert that it and other TPPs actually paid the inflated AWP set by Mallinckrodt for Acthar. (*Id.* ¶ 229). Consequently, it is unclear what was “false” about the AWP’s reported by Mallinckrodt to the industry publications.

Accompanying the distribution restrictions and the price increases, Plaintiff alleges that Mallinckrodt engaged in a fraudulent scheme to pump up demand for Acthar. In particular, Mallinckrodt aimed to convince doctors to prescribe Acthar not only for its FDA approved indications, which are mainly the acute treatment of rare conditions, but also as a long-term “maintenance medication” for a wider range of conditions, despite the absence of scientific evidence supporting such use. (*Id.* at ¶¶ 586–88).

In 2007, Mallinckrodt created a new position within the company: “Medical Science Liaison” or “MSL.” (*Id.* at ¶ 266). MSLs were deployed to speak to doctors about the safety and efficacy of Acthar for off-label indications. (*Id.*). However, Mallinckrodt also had the MSLs engage in promotional activities alongside sales representatives. (*Id.* at ¶ 269). When engaging in promotional activities, the MSLs made inaccurate claims about Acthar’s efficacy, for example by pushing physicians to prescribe Acthar to MS patients in lieu of Solu-Medrol, even though Mallinckrodt knew that Solu-Medrol was cheaper and more effective than Acthar at treating MS. (*Id.* at ¶ 270).

Mallinckrodt also cultivated “Key Opinion Leaders” or “KOLs” to create data to support its marketing efforts for Acthar. (*Id.* at ¶¶ 271–72). These KOLs included doctors who frequently prescribed Acthar and were paid by Mallinckrodt to produce research supporting a broad use of Acthar. (*Id.* at 274–76).

Mallinckrodt’s efforts resulted in many Acthar prescriptions being written by doctors who were being paid by the company. For example, in 2015 there were 300 prescribing providers who wrote more than ten Acthar prescriptions for Medicare and Medicaid patients, of whom at least 207 received payments from Mallinckrodt. (*Id.* at ¶¶ 280–82). Mallinckrodt also began a “white coat” marketing effort, working with doctors in fields in which Acthar was not an approved course

of treatment to generate data supporting its use. (*Id.* at ¶¶ 296–302). All the while, these doctors and Mallinckrodt knew that little scientific evidence actually supported the off-label uses of Acthar. (*Id.* at ¶ 448).

UBC employees also misrepresented the safety and efficacy of Acthar to patients and doctors. (*Id.* at ¶¶ 374–75). Further, UBC aids Mallinckrodt in running the “Patient Assistance Program” or “PAP,” the aim of which is to make Acthar free to patients by subsidizing their copayments. (*Id.* at ¶ 379). To achieve this aim, Mallinckrodt had a foundation called the Chronic Disease Fund (“CDF”) establish “patient assistance” funds that would be used for Acthar copayments only. (*Id.* at ¶ 381). Next, Mallinckrodt funded these patient assistance funds. (*Id.*). When patients or physicians submitted ASAP start forms to UBC, UBC would automatically provide these patients with an offer of copay assistance through the CDF. (*Id.* at ¶ 382).

Plaintiff alleges that Pratta participated in Mallinckrodt’s misleading marketing efforts by hosting dinners for KOLs to encourage the promotion of Acthar for off-label dosing. (*Id.* at ¶ 412). Specifically, on February 15, 2013 and on March 15, 2013, Pratta hosted dinners at which she an Acthar KOL promoted Acthar for an unapproved five-day dosing regimen to various other doctors. (*Id.* at ¶¶ 413–12).

D. Anticompetitive Acquisitions

While Mallinckrodt raised the price of Acthar in the late 2000s and early 2010s, Novartis AG (“Novartis”) was busy developing a potential competitor, Synacthen Depot (“Synacthen”), a synthetically derived ACTH medication. (*Id.* at ¶ 476). Although Synacthen was used outside the United States, it did not yet have FDA approval. (*Id.*). Mallinckrodt attempted to buy the rights to Synacthen in 2009 but did not succeed. (*Id.*).

In 2013, Novartis agreed to sell Synacthen to Retrophin, Inc. (“Retrophin”) for \$16 million. (*Id.* at ¶ 477). Rather than let the sale go through, Mallinckrodt intervened in the bidding process at the last minute, ultimately agreeing to acquire the rights to Synacthen for somewhere between \$135 million and \$300 million. (*Id.* at ¶¶ 524). After acquiring Synacthen, Mallinckrodt never took any steps to bring it to market in the United States. (*Id.* at ¶¶ 481, 534).

In January 2014, Retrophin sued Mallinckrodt for antitrust violations relating to the Synacthen acquisition, as did the Federal Trade Commission (“FTC”) in 2017. (*Id.* at ¶¶ 526–29). Mallinckrodt ultimately settled the Retrophin lawsuit for \$15.5 million, and the FTC lawsuit for \$100 million. (*Id.* at ¶¶ 530, 536). The FTC also required Mallinckrodt to sublicense the rights to Synacthen to another company that could then attempt to bring Synacthen to market. (*Id.* at ¶ 481).⁴

Around the same time that Mallinckrodt moved to fend off the horizontal competitive threat posed by Synacthen, Mallinckrodt also worked to secure its vertical supply chain. Since 2003, BioVectra Inc. (“BioVectra”) has been the only supplier of the Acthar Active Pharmaceutical Ingredient (“API”). (*Id.* at ¶ 564). In January 2013, Mallinckrodt purchased BioVectra. (*Id.*). Plaintiff alleges that the BioVectra acquisition gave Mallinckrodt the ability to deny any potential horizontal competitors access to the necessary samples of the Acthar API they would need to secure FDA approval of an Acthar generic drug. (*Id.* at ¶¶ 564-65).

E. Related Lawsuits

Since 2012, there have been a number of lawsuits filed against Mallinckrodt and Express Scripts related to the conduct described above. The Court limits its discussion to the four cases the

⁴ While the existence of these settlement agreements cannot be used to prove the validity of Plaintiff’s claims, there is no need to strike them from the Amended Complaint as Mallinckrodt urges the Court to do. *See Goode v. LexisNexis Risk & Info. Analytics Grp., Inc.*, 284 F.R.D. 238, 243 (E.D. Pa. 2012) (explaining that “[r]elief under Rule 12(f) is generally disfavored and will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues in the case” (internal quotations omitted)).

parties have identified as being especially salient to the pending Motion to Transfer and Motion to Stay.

i. The Qui Tam Suits

In 2012, Pratta and another Mallinckrodt employee, Charles Strunck, filed a *qui tam* lawsuit against Mallinckrodt in the Eastern District of Pennsylvania. *See* Fourth Amended Complaint, *United States ex rel. Pratta v. Questcor Pharm., Inc.*, No. 12-175 (E.D. Pa. June 13, 2017) (Doc. No. 40). This lawsuit principally seeks to recover damages on behalf of the United States and various states and municipalities for violations of the federal False Claims Act, 31 U.S.C. § 3729, and state law equivalents due to Mallinckrodt's fraudulent marketing of Acthar. *Id.* In 2013, another Mallinckrodt employee, Scott Clark, filed a similar *qui tam* complaint in the Eastern District of Pennsylvania. *See* Sealed Complaint, *United States ex rel. Clark v. Questcor Pharm., Inc.*, No. 13-1776 (E.D. Pa. Apr. 4, 2013) (Doc. No. 1). In March 2019, the United States elected to intervene in both cases, which were subsequently consolidated for further proceedings. *See* Order to Consolidate, *United States ex rel. Pratta v. Questcor Pharm., Inc.*, No. 12-175 (E.D. Pa. July 8, 2019) (Doc. No. 70).

ii. The Rockford Case

In April 2017, the City of Rockford, Illinois and Acument Global Technologies Inc., represented by the same counsel as Plaintiff in this case, filed a class action complaint against Mallinckrodt and Express Scripts in the Northern District of Illinois. *City of Rockford v. Mallinckrodt ARD, Inc.*, No. 17-50107 (N.D. Ill. Apr. 6, 2017) (Doc. No. 1). After a considerable amount of procedural back and forth, the plaintiffs filed a second amended complaint which alleged violations of federal and state antitrust and consumer protection laws, the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, and various other state

laws. *See City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 743 (N.D. Ill. 2019). In January 2019, the *Rockford* court granted in part and denied in part defendants' motions to dismiss, permitting the City of Rockford's federal and state law antitrust claims to survive. *Id.* at 778. The case does not involve any claims under New Jersey law.

iii. *The MSP Case*

In October 2017, MSP Recovery Claims, Series LLC filed a class action complaint against Mallinckrodt and Express Scripts in the Central District of California, which was transferred to the Northern District of Illinois in January 2018 to be coordinated with the *City of Rockford* case. *See MSP Recovery Claims, Series LLC v. Mallinckrodt ARD Inc.*, No. 17-7928, 2018 WL 2589014 (C.D. Cal. Jan. 17, 2018). This lawsuit brings claims for violations of both the federal Sherman Antitrust Act, 15 U.S.C. §§ 1–3, as well as a number of state antitrust and consumer protection statutes relating to the defendants' marketing, distribution, and pricing of Acthar. Redacted Second Amended Complaint, *MSP Recovery Claims, Series LLC v. Mallinckrodt ARD Inc.*, No. 20-50056 (N.D. Ill. July 2, 2020) (Doc. No. 361). The *MSP* case does not bring any claims under New Jersey law.

iv. *The Steamfitters Case*

In July 2019, Steamfitters Local Union No. 420, represented by the same counsel as Plaintiff, filed a class action complaint against Mallinckrodt and UBC in the Eastern District of Pennsylvania. Complaint, *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC*, No. 19-3047 (E.D. Pa. July 12, 2019) (Doc. No. 1). The complaint alleges violations of the federal RICO statute and a number of state consumer protection laws relating to Mallinckrodt and UBC's marketing and distribution of Acthar. *Id.* The complaint does not bring any claims under New Jersey law. *Id.* On December 19, 2019, the *Steamfitters* court issued a one-page order denying

defendants' motions to dismiss, providing virtually no explanation for its decision. *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC*, No. 19-3047 (E.D. Pa. Dec. 19, 2019).

F. Procedural History of This Case

Plaintiff filed its initial complaint on November 22, 2019, in the New Jersey Superior Court. (Doc. No. 1 at ¶ 2). On January 6, 2020, Mallinckrodt timely removed. (*Id.* at ¶ 21). On January 15, 2020, Plaintiff filed its Motion to Transfer the Case to the Eastern District of Pennsylvania. On January 24, 2020, Mallinckrodt filed a Motion to Stay the case and Express Scripts filed a Motion to Dismiss. Mallinckrodt filed its own Motion to Dismiss on January 27, 2020, as did Pratta on January 29, 2020.

Plaintiff failed to timely respond to Express Scripts' Motion to Dismiss, instead filing a Motion for an Extension of Time (Doc. No. 35) to respond until after the Court had ruled on the Motion to Transfer and the Motion to Stay. The Court granted Plaintiff's request in part, allowing it "until March 2, 2020 to file its *opposition briefs* in response to the Motions to Dismiss." (Doc. No. 39) (emphasis added). Instead of filing opposition briefs, Plaintiff filed its Amended Complaint on February 20, 2020. (Doc. No. 40). In response, Mallinckrodt and Express Scripts filed a Joint Motion to Strike the Amended Complaint (Doc. No. 41). The Court set an accelerated briefing schedule, requiring Plaintiff to respond on or before March 3, 2020. (Doc. No. 42). Pratta then filed her own Motion to Strike (Doc. No. 43).

Plaintiff chose to keep its options open by filing opposition briefs to all three pending Motions to Dismiss and the Motions to Strike on March 3. (Doc. Nos. 44, 45, 46, 47). Mallinckrodt and Express Scripts then filed Motions to Dismiss the Amended Complaint on March 5, 2020 (Doc. Nos. 49, 50), and Pratta filed a Motion to Dismiss the Amended Complaint (Doc. No. 55) on March 11, 2020.

Plaintiff's Amended Complaint has seven counts: Count I brings a claim under the New Jersey Consumer Fraud Act ("NJCFRA"), N.J.S.A. 56:8-1, *et seq.*; Count II brings a claim under the New Jersey Antitrust Act ("NJAA"), N.J.S.A. 56:9-1, *et seq.*; Count III alleges violations of the New Jersey RICO statute ("NJ RICO"), N.J.S.A. 2C:41-2(c); Count IV alleges conspiracy to violate NJ RICO under N.J.S.A. 2C:41-2(d); Count V alleges negligent misrepresentation; Count VI alleges civil conspiracy; and Count VII alleges unjust enrichment.

II. MOTION TO TRANSFER AND MOTION TO STAY

Plaintiff argues that this case should be transferred to the Eastern District of Pennsylvania so that it can be coordinated with the ongoing *qui tam* and *Steamfitters* lawsuits. Mallinckrodt and Express Scripts oppose Plaintiff's motion, and Mallinckrodt instead asserts that this case should be stayed while those lawsuits and the coordinated *City of Rockford* and *MSP* cases play out. Both sides assert that the "first-filed" rule applies, enabling the Court to take their preferred course of action. They are wrong.

A. The "First-Filed" Rule

The first-filed rule mandates that, "in all cases of concurrent jurisdiction, the court which first has possession of the subject must decide it." *Samsung Elecs. Co., Ltd. v. Imperium Holdings (Cayman), Ltd.*, 764 F. App'x 199, 200 (3d Cir. 2019) (quoting *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir. 1941)). The rule applies when the first-filed case is "materially on all fours" with the second-filed case in a way that is basically determinative of the second-filed case. *Grider v. Keystone Health Plan Ctr., Inc.*, 500 F.3d 322, 333 n.6 (3d Cir. 2007); *see also Complaint of Bankers Tr. Co. v. Chatterjee*, 636 F.2d 37, 40 (3d Cir. 1980) (noting that "[w]hen the claims, parties, or requested relief differ, deference may not be appropriate"). However, the "rule" is not to be applied woodenly, providing district courts with discretion to

dismiss, stay, transfer or continue to adjudicate the later-filed case. *See EEOC v. Univ. of Pa.*, 850 F.2d 969, 976–77 (3d Cir. 1988); *Maximum Human Performance, Inc. v. Dymatize Enters., Inc.*, No. 09-235, 2009 WL 2778104 (D.N.J. Aug. 27, 2009).

When determining whether two or more cases are materially on all fours with each other, courts look to both the subject-matter of the lawsuits and the identities of the parties. If the factual allegations in the two cases are the same, minor differences in the causes of action and remedies sought are insufficient to prevent application of the first-filed rule. *See Maximum Human Performance*, 2009 WL 2778104 at *4 (holding that the first-filed rule applied when the two actions were brought under different statutes but related to the same subject-matter); *Palagan v. NVIDIA Corp.*, 2015 WL 5025469 at *4 (E.D. Pa. 2015). Similarly, the parties to the two lawsuits need not be identical, but only “essentially the same.” *Abushalieh v. Am. Eagle Express*, 716 F. Supp. 2d 361, 366 (D.N.J. 2010) (internal quotation omitted).

However, courts generally decline to apply the first-filed rule if there are differences in the causes of action *and* the identities of the parties. *See Atanassov v. Amspec Servs., LLC*, 2016 WL 740269, at *3 (finding that class action on behalf of inspectors and dispatchers for Fair Labor Standards Act (“FLSA”) violations was not duplicative of suit only on behalf of inspectors seeking relief under the FLSA *and* state law); *Abushalieh*, 716 F. Supp. 2d at 365 (finding that FLSA collective action on behalf of delivery drivers in several states including Pennsylvania was not duplicative of earlier filed class action seeking relief under Pennsylvania wage and hour laws on behalf of Pennsylvania delivery drivers); *see also Glover v. Ferrero USA, Inc.*, No. 11-1086, 2011 WL 5007805, at *5 (D.N.J. Oct. 20, 2011) (holding that first-filed rule did not apply where one action set forth nationwide class claims under California law while the other set forth nationwide class claims under New Jersey law).

This case exclusively involves claims under New Jersey law by a class of New Jersey citizens. (FAC at ¶¶ 1, 420). While the *qui tam*, *City of Rockford*, *MSP*, and *Steamfitters* cases all involve similar factual allegations against Mallinckrodt and Express Scripts and rely on analogous causes of action, none of them bring claims under New Jersey law, and none of them involve an exclusive class of New Jersey residents. Further, Pratta is only named as a defendant in this action. *See Kedia v. Jamal*, No. 06-6054, 2007 WL 1239202, at *3 (D.N.J. Apr. 25, 2007) (finding that first-filed rule did not apply where individual was only named as a defendant in one case). And although Defendants accuse Plaintiff of forum-shopping, (Doc. No. 16-4 at 5), the Court has no authority to apply the first-filed rule to combat forum-shopping “when the rule’s narrow requirements are not met.” *Atanassov*, 2016 WL 740269, at *3 (noting that forum-shopping may be a reason to retain jurisdiction despite applicability of the first-filed rule but is not a sufficient reason to apply the rule in the first instance).

B. Transfer Pursuant to 28 U.S.C. § 1404(a)

In the alternative, Plaintiff urges the Court to transfer the case to the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1404(a). (Doc. No. 12-1 at 16–20). “For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented.” 28 U.S.C. § 1404(a). In contrast to transfer of venue under 28 U.S.C. § 1406, where the court finds the original venue improper, transfer of venue is done under § 1404(a) “for the convenience of the parties even if the court finds that the original venue is proper.” *Ferratex, Inc. v. U.S. Sewer & Drain, Inc.*, 121 F. Supp. 3d 432, 436 (D.N.J. 2015).

The decision whether to transfer an action pursuant to Section 1404(a) is within the Court’s discretion. *Kisano Trade & Invest Ltd. v. Lemster*, 737 F.3d 869, 872 (3d Cir. 2013); *Lepre v.*

Lukus, 602 F. App'x 864, 868 (3d Cir. 2015), *cert. denied*, 575 U.S. 969 (2015). The party seeking transfer of venue bears the burden of establishing that transfer is warranted and must submit “sufficient information in the record” to facilitate the Court’s analysis. *Hoffer v. InfoSpace.com, Inc.*, 102 F. Supp. 2d 556, 572 (D.N.J. 2000). Before transferring venue, the Court must articulate specific reasons for its decision. *Lawrence v. Xerox Corp.*, 56 F. Supp. 2d 442, 451 (D.N.J. 1999).

Under 28 U.S.C. § 1404(a), the court must take into account a wide range of public and private interests when determining if a transfer to a new venue is appropriate. The Third Circuit has identified the following private factors as being significant to the § 1404(a) analysis:

[1] [P]laintiff’s forum preference as manifested in the original choice; [2] the defendant’s preference; [3] whether the claim arose elsewhere; [4] the convenience of the parties as indicated by their relative physical and financial condition; [5] the convenience of the witnesses—but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and [6] the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum).

Jumara v. State Farm Ins. Co., 55 F.3d 873, 879 (3d Cir. 1995) (citations omitted). Among the public factors that courts consider are the following:

[1] [T]he enforceability of the judgment; [2] practical considerations that could make the trial easy, expeditious, or inexpensive; [3] the relative administrative difficulty in the two fora resulting from court congestion; [4] the local interest in deciding local controversies at home; [5] the public policies of the fora; and [6] the familiarity of the trial judge with the applicable state law in diversity cases.

Id. at 879–80 (citations omitted). The movant bears “[t]he burden of establishing the need for transfer.” *Id.* at 879 (internal quotations omitted).

Defendants concede that this case could have been brought in the Eastern District of Pennsylvania but assert that the private and public interests counsel against transfer. (Doc. No. 30 at 19–25). The Court agrees with Defendants. All of the private interests weigh against transfer: Plaintiff initially chose to litigate in New Jersey, Defendants wish to continue litigating here,

Plaintiff and the class members' claims all arose in New Jersey, and as the James A. Byrne Courthouse in Philadelphia is visible from the upper floors of the Mitchell H. Cohen Courthouse in Camden, the Court cannot conceive of any meaningful inconvenience or difficulty posed by continued litigation in New Jersey as opposed to the Eastern District of Pennsylvania. As Plaintiff makes no argument that any of the public factors cut in its favor, the Court will deny its Motion. And because the first-filed rule does not apply, the Court will also deny Mallinckrodt's Motion to Stay.

III. INITIAL MOTIONS TO DISMISS AND MOTIONS TO STRIKE

Under Federal Rule of Civil Procedure 15(a)(1)(B), a plaintiff may amend its complaint as a matter of right within twenty-one days after service of a Rule 12(b) motion. If the plaintiff tarries, it may amend its complaint "only with the opposing party's written consent or the court's leave." Fed.R.Civ.P. 15(a)(2). However, the Court "should freely give leave when justice so requires." *Id.*; *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990) (asserting that Rule 15 should be applied liberally to avoid deciding cases on technicalities). Courts generally only deny leave to amend in certain circumstances, such undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice, or clear futility of the amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Fed. Deposit Ins. Corp. v. Bathgate*, 27 F.3d 850, 874 (3d Cir. 1994).

In this case, Plaintiff filed its Amended Complaint on February 25, 2020—26 days after Express Script's Motion to Dismiss was filed, 23 days after Mallinckrodt's Motion to Dismiss was filed, but exactly 21 days after Pratta's Motion to Dismiss was filed. *See* Fed.R.Civ.P. 6(a)(1)(A) (explaining that when calculating deadlines under the Rules, one must "exclude the day of the event that triggers the period"). As such, Plaintiff's Amended Complaint was timely as to Pratta.

Further, Mallinckrodt and Express Scripts concede that the Amended Complaint does not materially change any of the allegations against them, (Doc. No. 41-1 at 4), and their briefs in support of their Motions to Dismiss the Amended Complaint are identical to their original motions, save for changes to the paragraph numbers in their citations to the Amended Complaint. Consequently, Mallinckrodt and Express Scripts have no material claim of prejudice.

While the Court regrets that the briefing became so confused, at this point the simplest way forward is clearly to permit the Amended Complaint to stand and to adjudicate the Motions to Dismiss the Amended Complaint. Therefore, the Motions to Strike will be denied and the initial Motions to Dismiss will be denied as moot.⁵

IV. MALLINCKRODT AND EXPRESS SCRIPTS' MOTIONS TO DISMISS THE AMENDED COMPLAINT

A. Legal Standard

i. Rule 12(b)(6) Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) allows a court to dismiss an action for failure to state a claim upon which relief can be granted. When evaluating a motion to dismiss, “courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. Cty.*

⁵ Hypothetically, if the Court were to grant the motions to strike and then grant the initial motions to dismiss, such dismissal would almost surely be without prejudice. As a result, Plaintiff would be able to file an amended complaint anyway. Therefore, no one really has anything to gain by striking the Amended Complaint and adjudicating the initial Motions to Dismiss as opposed to proceeding to simply adjudicate the Motions to Dismiss the Amended Complaint.

The Court notes that Plaintiff has failed to file opposition briefs to Mallinckrodt and Express Scripts' Motions to Dismiss the Amended Complaint. As many months have gone by, the Court assumes that Plaintiff has no interest in doing so. Nevertheless, because Mallinckrodt and Express Scripts' Motions to Dismiss the Amended Complaint are virtually identical to their initial Motions to Dismiss, the Court will treat Plaintiff's Opposition briefs to those motions as if they were in response to the later filed motions.

of *Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). In other words, a complaint survives a motion to dismiss if it contains enough factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

To make this determination, courts conduct a three-part analysis. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the Court must “tak[e] note of the elements a plaintiff must plead to state a claim.” *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the Court should identify allegations that, “because they are no more than conclusions, are not entitled to the assumption of truth.” *Id.* (quoting *Iqbal*, 556 U.S. at 680). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* (quoting *Iqbal*, 556 U.S. at 678). Finally, “when there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.” *Id.* (quoting *Iqbal*, 556 U.S. at 679). A complaint cannot survive a motion to dismiss where a court can only infer that a claim is merely possible rather than plausible. *Id.*

ii. *Rule 9(b)*

Federal Rule of Civil Procedure 9(b) provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” To satisfy Rule 9(b)’s particularity requirement, a plaintiff must: (1) “state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which [it is] charged”; and (2) “plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.” *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (internal citations omitted). As the Third Circuit has

explained, Rule 9(b) requires a plaintiff to provide “the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.” *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (internal quotations omitted).

B. Collateral Estoppel

As discussed above, in January 2019 the *City of Rockford* court denied in part motions to dismiss filed by Mallinckrodt and Express Scripts, permitting the City of Rockford’s antitrust claims relating to Acthar to survive, and in December 2019 the *Steamfitters* court denied motions to dismiss filed by Mallinckrodt and UBC, allowing the plaintiff’s federal RICO claims to survive. In light of these rulings, Plaintiff contends that Mallinckrodt and Express Scripts are barred by the doctrine of collateral estoppel from seeking dismissal of Plaintiff’s NJAA and NJ RICO claims. (Doc. No. 44 at 18; Doc. No. 45 at 17–18).

Plaintiff’s argument is absurd. “Collateral estoppel bars relitigation of an issue where (1) the identical issue was decided in a prior adjudication; (2) there was a final judgment on the merits; (3) the party against whom the bar is asserted was a party or in privity with a party to the prior adjudication; and (4) the party against whom the bar is asserted had a full and fair opportunity to litigate the issue in question.” *Gross-Quatrone v. Mizdol*, 811 F. App’x 95, 97, 97 n.4 (3d Cir. 2020) (internal quotation omitted) (noting that “[t]he elements for issue preclusion under federal common law and New Jersey law are almost identical” (internal quotation omitted)). Neither the *City of Rockford* court nor the *Steamfitters* court has yet issued a “final judgment,” meaning that the doctrine of collateral estoppel is obviously inapplicable. Indeed, these rulings have no binding precedential effect beyond their capacity to persuade. *Daubert v. NRA Grp., LLC*, 861 F.3d 382, 395 (3d Cir. 2017) (noting that “*stare decisis* does not compel one district court judge to follow

the decision of another” (internal quotation omitted)). While the *City of Rockford* court issued a thorough opinion that the Court has carefully considered, the *Steamfitters* court’s one-page order has no persuasive power. With these principles in mind, the Court turns to the merits of Plaintiff’s various claims.

C. NJCFA (Count I)

The *prima facie* case for an NJCFA violation has three elements: “(1) unlawful conduct by defendant; (2) an ascertainable loss by plaintiff; and (3) a causal relationship between the unlawful conduct and the ascertainable loss.” *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 749 (N.J. 2009). Because the NJCFA was enacted to protect “consumers,” “business entities” may only bring claims under the act when they are in a “consumer oriented situation.” *J & R Ice Cream Corp. v. Cal. Smoothie Licensing Corp.*, 31 F.3d 1259, 1273 (3d Cir. 1994) (internal quotation omitted). A business entity is in a “consumer oriented situation” when it “uses economic goods, and so diminishes or destroys their utilities.” *Cent. Reg’l Emp. Benefit Fund v. Cephalon*, No. 09-3418, 2009 WL 3245485, at *3 (D.N.J. Oct. 7, 2009) (internal quotation omitted).

Because TPPs, like Plaintiff, “essentially serve as middlemen or insurers, paying all or part of the cost of a beneficiary’s drugs in return for a stream of payments from the beneficiary,” they are not “consumers entitled to sue under the NJCFA.” *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 WL 2043604, at *32 (D.N.J. July 10, 2009); *see also MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, No. 18-2211, 2019 WL 1418129, at *18 (D.N.J. Mar. 29, 2019) (finding TPP plaintiffs lacked standing to sue under the NJCFA); *Cephalon*, 2009 WL 3245485, at *3) (same). As Plaintiff cannot plead that it is not a TPP, any attempt to amend would be futile, and so this claim will be dismissed with prejudice.

See Cephalon, 2009 WL 3245485, at *3 (dismissing TPP plaintiffs' NJCFA claims with prejudice).

D. NJAA (Count II)

Plaintiff's antitrust claims focus on the ASAP program, through which Mallinckrodt and Express Scripts fixed Acthar's price and restricted its distribution, and on the Synacthen acquisition, by which Mallinckrodt prevented the entry of a new competitor into the ACTH market. Plaintiff is proceeding solely under the NJAA, specifically invoking the act's provisions barring anticompetitive agreements, N.J.S.A. 56:9–3, and conspiracy to monopolize, N.J.S.A. 56:9–4(a).⁶ (FAC at ¶ 623). Because New Jersey courts “follow federal antitrust law in interpreting [the NJAA],” *Wilson v. General Motors Corp.*, 921 A.2d 414, 416 (N.J. 2007) (citing N.J.S.A. 56:9–18), the Court relies on caselaw applying the federal antitrust statutes when analyzing Plaintiff's claims.

As with Sherman Act Section 1 claims, a plaintiff bringing a Section 56:9–3 claim must allege: “(1) concerted action by the defendants; [(2)] that produced anticompetitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action.” *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 253 (3d Cir. 2010). Similarly, to state a conspiracy to monopolize claim under Section 56:9–4(a), a plaintiff must allege: “(1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged.” *Id.*

⁶ Like Sherman Act Section 2, NJAA Section 56:9–4(a) prohibits three distinct types of conduct—monopolization, attempted monopolization, and conspiracy to monopolize. Neither the Amended Complaint nor Plaintiff's briefing explicitly states which of these theories Plaintiff is pursuing. However, Plaintiff's heavy reliance on the *City of Rockford* case, where the plaintiffs apparently only pursued a conspiracy to monopolize theory, 360 F. Supp. 3d at 755–56, leads the Court to assume that Plaintiff is similarly only pursuing a conspiracy theory. If Plaintiff wishes to pursue a monopolization and/or attempted monopolization theory, it must attempt to amend its Amended Complaint to make that desire clear.

Because the relevant elements largely overlap for the theories of anticompetitive harm Plaintiff is pursuing, the Court analyzes Plaintiff's anticompetitive agreement and conspiracy to monopolize claims in tandem. Ultimately, the Court finds that Plaintiff has a viable claim against Mallinckrodt for its acquisition of Synacthen, but that its other antitrust claims fail.

i. Claims Regarding the ASAP Program

While some types of restraints “are unreasonable *per se* because they always or almost always tend to restrict competition and decrease output,” most restraints are evaluated under the “rule of reason,” which requires the Court to assess whether the restraint actually harms consumers. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2283–84 (2018) (internal quotations omitted). The restraints enforced by the ASAP program are vertical restraints because they were “imposed by agreement between firms at different levels of distribution,” and virtually all vertical restraints are evaluated under the rule of reason. *Id.* Plaintiff offers no reason why the rule of reason should not apply here. Consequently, Plaintiff must allege that the ASAP program has an anticompetitive effect within the relevant product and geographic markets.

Mallinckrodt and Express Scripts make three main arguments as to why Plaintiff's challenge to the ASAP Program fails. First, Mallinckrodt contends that Plaintiff has failed to establish a plausible product market. (Doc. No. 49-2 at 29–30). Second, Mallinckrodt asserts that Plaintiff has not provided sufficient allegations of an agreement between Mallinckrodt and Express Scripts to fix prices. (*Id.* at 23–25). Third, Mallinckrodt and Express Scripts both argue that Plaintiff has not adequately pleaded any anticompetitive effects stemming from the ASAP Program. (*Id.* at 20–23, 26–27; Doc. No. 50-1 at 34–37).

1. Product Market

Plaintiffs challenging vertical restraints under the rule of reason must show that those restraints harmed competition in the relevant product market, defined as “the area of effective competition” or “the arena within which significant substitution in consumption or production occurs.” *Am. Express*, 138 S. Ct. at 2285, 2285 n.7 (internal quotations omitted). The market must “reflect[] commercial realities.” *Id.* at 2285 (internal quotation omitted). Typically, product market definition is a question of fact that cannot be adjudicated until after discovery, but a motion to dismiss may be granted “[w]here the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products.” *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997).

Plaintiff defines the relevant product market in this case as “ACTH drugs,” with Acthar being the only product currently available in the market. As Mallinckrodt points out, this proposed market seems troubling at first, because it excludes the generic drugs that Plaintiff repeatedly alleges are equally effective for the treatment of many of Acthar’s approved indications. (FAC at ¶¶ 115, 117). However, Plaintiff also alleges that patients and physicians do not substitute these drugs for Acthar; indeed, Mallinckrodt was able to increase sales in the theoretically competitive indications even as it dramatically raised prices. (FAC at ¶¶ 286, 399–405). Given the absence of cross-elasticity of demand between Acthar and its generic alternatives, the commercial reality seems to be that Acthar really is in its own market. *See United Food & Commercial Workers Local 1776 & Participating Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1171–72 (N.D. Cal. 2017) (noting that “in the pharmaceutical context courts have limited the market to similar classes or drugs or even more narrowly, to the brand product itself in absence of cross-elasticity evidence” (citing *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d

Cir. 1978); *FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1240 (8th Cir. 2011); *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004))). Further, Plaintiff also alleges that Acthar is uniquely effective at treating IS, an indication for which it faces zero competition. (FAC at ¶¶ 140, 175–75). As ACTH drugs are insulated from competition and have a salient distinguishing characteristic, Plaintiff’s proposed product market is adequate to survive a motion to dismiss.

2. Existence of an Agreement

A “single entity” is incapable of conspiring with itself to unreasonably restrain trade. *Am. Needle, Inc. v. NFL*, 560 U.S. 183, 194–95 (2010). Because “‘substance, not form, should determine whether an entity is capable of conspiring,’” legally separate entities are sometimes considered single entities for antitrust conspiracy purposes. *Id.* at 194–95 (quoting *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984)). For example, “a parent corporation and its wholly owned subsidiary ‘are incapable of conspiring with each other.’” *Am. Needle*, 560 U.S. at 194 (quoting *Copperweld*, 467 U.S. at 777)). When making this determination, the key question is “whether there is a contract, combination, or conspiracy amongst separate economic actors pursuing separate economic interests.” *Am. Needle*, 560 U.S. at 195 (internal quotation omitted).

Under this doctrine, a corporation is sometimes considered to be a single entity with its sales agent, such that the two cannot enter into a price-fixing conspiracy. *See United States v. General Elec. Co.*, 272 U.S. 476, 488 (1926) (holding that “genuine contracts of agency” cannot violate the Sherman Act); *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 21–23 (1964) (finding that a sham consignment relationship did not shield the defendant from antitrust liability); *see also Am. Needle*, 560 U.S. at 195 n.4 (holding that the *Copperweld* functional test should be used to

determine if an agency relationship is “genuine” and therefore immune from antitrust scrutiny). “Genuine” agency relationships are immunized because “one of the benefits of manufacturing a good is to set the price by which it is sold” meaning “it is only sensible not to deprive the manufacturer of its right if, for reasons of efficiency, it chooses to use agents that are loyal to it rather than employees.” *Valuepest.com of Charlotte v. Bayer Corp.*, 561 F.3d 282, 288 (4th Cir. 2009). When determining whether an agency relationship is genuine or merely a sham, courts consider the “distribution of business risks,” “the economic justification for the agency relationship,” and “whether the agency agreement is a product of coercion.” *Id.* at 290–91 (citing *Day v. Taylor*, 400 F.3d 1272, 1278 (11th Cir. 2005)).

In this case, Plaintiff alleges that Mallinckrodt sells Acthar on consignment, with Express Scripts simply serving as its sales agents. (FAC at ¶ 191). As Plaintiff describes it, possession never passes from Mallinckrodt to Express Scripts, but only from Mallinckrodt to the consumer directly, and Plaintiff specifically alleges that Mallinckrodt always bears the full risk of loss. (*Id.*). Further, Plaintiff does not allege that Mallinckrodt coerced Express Scripts into this relationship. Thus, Plaintiff has pleaded a genuine agency relationship between Mallinckrodt and Express Scripts, meaning that they are a single entity for price-fixing conspiracy purposes. *See Day*, 400 F.3d at 1277–78 (finding that U-Haul dealers were genuine agents where U-Haul bore the costs of the equipment and exercised no coercive power over its dealers). But while an agency relationship requires pricing agreements, it does not require exclusivity, and therefore this reasoning does not preclude Plaintiff’s challenge to Express Script’s exclusive distributorship of Acthar.

3. Anticompetitive Effects of the Exclusive Distributorship

Plaintiff fails to show that Express Scripts' exclusive distributorship had an adverse effect on competition.⁷ Exclusive distributorship arrangements are often upheld on antitrust challenges because they can have substantial procompetitive benefits, such as “to assure supply, price stability, outlets, investment, best efforts, or the like.” *Race Tires Am, Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010) (internal quotation omitted). Indeed, the Second Circuit has gone so far as to say that “exclusive distributorship arrangements are presumptively legal.” *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 30 (2d Cir. 2006). However, such arrangements are not exempt from antitrust scrutiny, as they have the potential to “exclude competitors or new entrants from a needed supply, or to allow one supplier to deprive other suppliers of a market for their goods.” *Geneva Pharm.*, 386 F.3d at 508.

Plaintiff offers two theories as to why Express Scripts' exclusive distribution of Acthar is anticompetitive. First, Plaintiff argues that exclusive distribution through Express Scripts prevents other distributors from pushing back on Mallinckrodt's aggressive price increases, allowing Acthar's price to shoot into the stratosphere. Yet this theory flies in the face of conventional economic wisdom, as normally a manufacturer prefers to have multiple distributors competing for its products, as such competition will tend to support higher prices. *See E & L Consulting*, 472 F.3d at 30 (explaining that “a firm with a monopoly at the retail distribution level will further reduce output to maximize its profits, thereby reducing the sales and profit of the monopoly manufacturer”). If there is something unique at play in the pharmaceutical distribution market, Plaintiff fails to explain what it is. Consequently, Plaintiff's first theory of anticompetitive harm is implausible.

⁷ For claims concerning exclusive distributorship arrangements, the analysis of Section 56:9–3's “anticompetitive effects” requirement is essentially the same as for Section 56:9–4(a)'s “overt acts” requirement. *City of Rockford*, 360 F. Supp. 3d at 756. But reader beware—sometimes the analysis for these requirements can be quite different.

Second, Plaintiff contends that the exclusive distributorship served to keep potential competitors to Acthar, such as Synacthen, off the market. Notably, the *City of Rockford* court approved of this theory when denying Mallinckrodt and Express Scripts' motions to dismiss in that case. *See City of Rockford*, 360 F. Supp. 3d at 749 (explaining that "[t]he goal of the exclusive dealing arrangement was to . . . prevent a competitive product from entering the market. Express Scripts employed its market power to effectuate [this] goal[]" (internal quotation omitted)). The theory also finds some support from the Supreme Court's decision in *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007). In that case, the Court noted that resale price maintenance agreements can be abused by "[a] manufacturer with market power . . . to give retailers an incentive not to sell the products of smaller rivals or new entrants." *Id.* at 894 (citing Howard P. Marvel & Stephen McCafferty, *The Welfare Effects of Resale Price Maintenance*, 28 J. L. & Econ. 363, 366–68 (1985) (describing historical examples of how dominant manufacturers used resale price maintenance in conjunction with exclusivity agreements to induce distributor loyalty, and how those distributors accordingly refused to deal with new competitors to the manufacturers)). Although this case does not concern a resale price maintenance agreement, by making Express Scripts the exclusive distributor of Acthar and then dramatically increasing the price, Mallinckrodt may very well have hoped to incentivize Express Scripts to refuse to deal with its potential rivals.

However, there is no indication that Express Scripts actually took any steps to harm or exclude any of Acthar's potential competitors. *Cf. Geneva Pharm.*, 386 F.3d at 492–93 (allowing challenge to exclusive dealing relationship between supplier and manufacturer to survive summary judgment where supplier actively dissuaded potential competitor to manufacturer from entering the market and lied about the existence of the exclusive dealing arrangement). Further, there is no

firm indication that any such steps would have actually prevented a potential competitor from entering the market, as Plaintiff makes no specific allegations concerning Express Scripts' market power. Consequently, Plaintiff's second theory of anticompetitive harm is not viable as currently pleaded.⁸ And without a viable theory harm, Plaintiff's Section 56:9–3 challenge to the ASAP Program must be dismissed.

ii. Synacthen Acquisition Claim Against Express Scripts

Plaintiff appears to suggest that Express Scripts was involved in Mallinckrodt's decision to acquire the rights to Synacthen from Novartis in 2013 in order to prevent Synacthen from coming to market. (FAC at ¶¶ 498–507, 631). An agreement between Mallinckrodt and Express Scripts as to who would acquire Synacthen could constitute bid-rigging, which is a *per se* antitrust violation. *United States v. Fischbach & Moore, Inc.*, 750 F.2d 1183, 1192 (3d Cir. 1984) (noting that bid-rigging is a *per se* violation of Sherman Act Section 1); *United States v. Joyce*, 895 F.3d 673, 677–79 (9th Cir. 2018) (same). However, Plaintiff would still need to adequately allege the existence of such an agreement.

“To adequately plead an agreement, a plaintiff must plead either direct evidence of an agreement or circumstantial evidence.” *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 225 (3d Cir. 2011). “Direct evidence of a conspiracy is evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted.” *Id.* By contrast, to succeed on a circumstantial approach, the plaintiff must plead parallel behavior on the part of the defendants that “raises a suggestion of a preceding agreement, not merely parallel conduct that could just as

⁸ Plaintiff may protest that even if Express Scripts did not directly refuse to deal with new entrants, the exclusive dealing relationship may still have induced it to cooperate in Mallinckrodt's illegal marketing scheme for Acthar. However, the Supreme Court has held that even when firms implement a vertical restraint in order to perpetrate an illegal fraud, the restraint cannot be condemned under antitrust law unless the plaintiff shows harm to competition. *See NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 137–138 (1998) (finding that plaintiff still needed to show anticompetitive harm from vertical boycott even though said boycott was part of an attempt to defraud a regulatory agency).

well be independent action.” *Twombly*, 550 U.S. at 557. In order to raise this suggestion, the plaintiff may rely on three “‘plus factors[]’ that tend to demonstrate the existence of an agreement: ‘(1) evidence that the defendant had a motive to enter into a price fixing conspiracy; (2) evidence that the defendant acted contrary to its interests; and (3) evidence implying a traditional conspiracy.’” *Burtch*, 662 F.3d at 227 (quoting *In re Insur. Brokerage Antitrust Litig.*, 618 F.3d 300, 322 (3d Cir. 2010)). Importantly, “[r]equiring plausibility to infer an agreement from circumstantial evidence ‘does not impose a probability requirement at the pleading stage; it simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of illegal agreement.’” *Burtch*, 662 F.3d at 227 (quoting *Twombly*, 550 U.S. at 556).

Plaintiff does not allege any direct evidence of an agreement between Mallinckrodt and Express Scripts relating to Synacthen. Rather, Plaintiff alleges that Express Scripts was complicit in the Synacthen acquisition because it did not “force Mallinckrodt to either bring Synacthen to market as a competitor to Acthar or license the drug to another company to compete with Acthar.” (FAC at ¶ 481). In support of its claim that Express Scripts had the power to force Mallinckrodt to bring Synacthen to market, Plaintiff notes that when Turing Pharmaceuticals, LLC (“Turing”) increased the price of Daraprim 5000%, Express Scripts worked with another drug manufacturer to develop a lower-cost alternative to Daraprim. (*Id.* at ¶¶ 460–63). By failing to counteract Mallinckrodt’s aggressive pricing strategy as it had done with Turing’s, Express Scripts acted contrary to its economic interest, at least according to Plaintiff.

However, this theory is constrained by Plaintiff’s own pleading, as it alleges that “[t]he only potential substitute [for Acthar] was Synacthen.” (FAC at ¶ 485). Plaintiff also alleges that Mallinckrodt’s 2013 purchase of BioVectra gave Mallinckrodt full control over the only supplier of the Acthar API, making it impossible to develop a generic ACTH competitor to Acthar. (FAC

at ¶ 564). These allegations indicate that there was no way for Express Scripts to develop a competitor drug after Mallinckrodt's acquisition of Synacthen, and Plaintiff describes no other way by which Express Scripts could have forced Mallinckrodt to bring Synacthen to market. Lacking any "plus factors," Plaintiff has not plausibly alleged the existence of an agreement between Mallinckrodt and Express Scripts regarding Synacthen, and thus Plaintiff's claim against Express Scripts must be dismissed.

iii. Synacthen Acquisition Claim Against Mallinckrodt

By contrast, there is no dispute that Mallinckrodt entered into an agreement with Novartis to acquire the rights to Synacthen. But as there is no *per se* rule against acquisitions, Plaintiff must establish that the acquisition had an adverse effect on competition in order to collect damages. Plaintiff must also "assert an antitrust injury[,] 'which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *EJ MGT LLC v. Zillow Grp., Inc.*, No. 18-584, 2019 WL 981649, at *4 (D.N.J. Feb. 28, 2019) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mart, Inc.*, 429 U.S. 477, 489 (1977)); see *Van Dyk Research Corp. v. Xerox Corp.*, 631 F.2d 251, 255 (3d Cir. 1980) (noting that an antitrust plaintiff must show that the defendant's "illegal conduct was a material cause of its injury").

Mallinckrodt's sole argument against its antitrust liability for the Synacthen acquisition is that Plaintiff cannot establish the causation element of antitrust injury. (Doc. No. 49-2 at 27–28). This argument fails. Plaintiff alleges that "[b]ut-for Mallinckrodt's acquisition of Synacthen, one of the three alternative bidders, including Retrophin, would have acquired Synacthen and pursued its plan to develop Synacthen for IS to compete directly with Acthar at a lower price." (FAC at ¶ 531). This allegation is sufficient for Plaintiff's claim to survive a motion to dismiss.

Mallinckrodt contends that Plaintiff's causation theory is too speculative because it is unclear whether Retrophin or another bidder could have actually brought Synacthen to market as a competitor to Acthar, particularly due to the difficulty of obtaining FDA approval. (Doc. No. 49-2 at 27–28). However, there are two reasons why Mallinckrodt's contentions do not prevail. First, assessing whether another firm could have successfully brought Synacthen to market is the sort of fact-intensive inquiry that is inappropriate to resolve on a motion to dismiss. *See Brader v. Allegheny General Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995) (noting that “the existence of ‘antitrust injury’ is not typically resolved through motions to dismiss”); *cf. Takeda Pharm. Co. Ltd. v. Zydus Pharm. (USA) Inc.*, 358 F. Supp. 3d 389, 398 (D.N.J. 2018) (explaining that “district courts within this Circuit have declined to hold that the absence of FDA approval creates a barrier to establishing the element of causation in a patent antitrust suit” and collecting cases).

Second, Mallinckrodt's argument presumes that Plaintiff may only pursue an actual potential competition theory with respect to Synacthen, rather than a perceived potential competition theory. *See United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 75 (D.D.C. 2017) (explaining that “[t]he perceived potential competition theory posits that if market participants believe that a firm outside of the market is likely to enter, that perception can have a procompetitive effect on the market (whether or not that firm is actually likely to enter)” (citing *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 624–25 (1974); *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 531–32 (1973) (adopting perceived potential competition doctrine))); *see also United States v. Penn-Olin Chem. Co.*, 378 U.S. 158, 174 (1964) (“The existence of an aggressive, well equipped and well financed corporation engaged in the same or related lines of commerce waiting anxiously to enter an oligopolistic market would be a substantial incentive to competition which cannot be underestimated.”). Plaintiff has alleged that Mallinckrodt perceived

Synacthen to be a potential competitor long before the acquisition, and its effort to keep Synacthen out of Retrophin's hands suggest that perceived Retrophin as a genuine competitive threat. (FAC at ¶¶ 504, 523–25). Due to this perception, a Synacthen-equipped Retrophin may have been able to constrain Mallinckrodt's pricing of Acthar, even if its chances of actually bringing Synacthen to market were slim. Whether Mallinckrodt really perceived Synacthen and Retrophin as potential competitors is an issue that will have to await discovery.

E. NJ RICO (Counts III)

In Count III of the Amended Complaint, Plaintiff brings a claim under N.J.S.A. 2C:41–2(c), which makes it “unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity.” Plaintiff alleges that Defendants made numerous misrepresentations when implementing the “distribution scheme,” the “pricing scheme,” an the “marketing scheme,” and that these fraudulent acts amounted to an illegal “pattern of racketeering activity” in violation of Section 2C:41–2(c). (FAC at ¶¶ 637–38).

To state an claim under Section 2C:41–2(c), the plaintiff must allege: “(1) the existence of an enterprise; (2) that the enterprise engaged in activities that affected trade or commerce; (3) that the defendant was employed by, or associated with the enterprise; (4) that the defendant participated in the conduct of the affairs of the enterprise; (5) that the defendant participated through a pattern of racketeering activity; and (6) that the plaintiff was injured as a result of the conspiracy.” *Marina Dist. Dev. Co., LLC v. Ivey*, 216 F. Supp. 3d 426, 436 (D.N.J. 2016). Further, the plaintiff must “make two related but analytically distinct threshold showings . . . (1) that the plaintiff suffered an injury to business or property; and (2) that the plaintiff's injury was

proximately caused by the defendant's [RICO] violation." *Maio v. Aetna, Inc.*, 221 F.3d 472, 483 (3d Cir. 2000).

New Jersey courts look to case law on the federal RICO statute when interpreting NJ RICO. *Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 510 (3d Cir. 2006). At the same time, "NJ RICO is broader in scope and is construed more liberally than the federal RICO statute." *Fimbel v. Fimbel Door Corp.*, No. 14-1915, 2014 WL 6992004, at *5–6 (D.N.J. Dec. 10, 2014) (citing *State v. Bisaccia*, 724 A.2d 836, 846 (N.J. Super. Ct. App. Div. 1999)).

i. Cognizable Injury

Plaintiff's theory of injury is that Defendants' various "schemes" fraudulently stoked demand for Acthar, caused Plaintiff to pay an inflated price. Express Scripts contends that this theory of injury is not a cognizable under NJ RICO, relying on the Third Circuit's decision in *Maio*, which rejected the plaintiffs' theory that they overpaid for a health insurance plan because they did not allege that the "health care they received . . . actually was compromised or diminished as a result of [defendant]'s management decisions challenged in the complaint." 221 F.3d at 488. Thus, Express Scripts contends that Plaintiff must allege that the dose of Acthar it purchased failed to perform as expected in order to satisfy NJ RICO's injury requirement. (Doc. No. 50-1 at 40).

However, in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, the Third Circuit held that a group of TPPs had suffered a cognizable RICO injury when they overpaid for a drug due to the manufacturer's deceptive marketing practices. 804 F.3d 633, 639–40 (3d Cir. 2015). The court distinguished *Maio* on the basis that while the *Maio* plaintiffs' injury depended on the quality of the health care they received under the defendant's insurance plan, the TPP's injury was solely due to the inflationary effect of the defendant's fraud on the price of the drug. *Id.* at 640 (explaining that "the fraudulent behavior alleged in [the plaintiffs'] complaint has

already occurred, and its effect on the price of [the drug] is not contingent on future events”). Therefore, far from being foreclosed by Third Circuit precedent, Plaintiff’s theory of injury has actually been explicitly endorsed.⁹ The Court will not dismiss Plaintiff’s NJ RICO claims on this basis.

ii. *Pattern of Racketeering Activity*

To show a “pattern of racketeering activity,” the plaintiff must allege “at least two incidents of racketeering conduct.” N.J.S.A. 2C:41–1(d)(1). Plaintiff alleges that Defendants have committed multiple instances of mail fraud, in violation of 18 U.S.C. § 1341, and wire fraud, in violation of 18 U.S.C. § 1343. The elements of mail fraud are : “(1) the existence of a scheme to defraud; (2) the use of the mails . . . in furtherance of the fraudulent scheme; and (3) . . . participation by the defendant with specific intent to defraud.” *United States v. Dobson*, 419 F.3d 231, 237 (3d Cir. 2005). Similarly, the elements of wire fraud are: “(1) the defendant’s knowing and willful participation in a scheme or artifice to defraud, (2) with the specific intent to defraud, and (3) the use of interstate wire communications in furtherance of the scheme.” *United States v. Andrews*, 681 F.3d 509, 528 (3d Cir. 2012) (internal quotation omitted). While “[e]xpress falsehoods lie at fraud’s core,” a “fraudulent or false representation may be effected by deceitful statements or half-truths or the concealment of material facts.” *United States v. Ferriero*, 866 F.3d 107, 120 (3d Cir. 2017) (internal quotation omitted). Allegations of mail fraud or wire fraud must meet Rule 9(b)’s pleading standard. *Marangos v. Swett*, 341 F. App’x 752, 757 (3d Cir. 2009). Plaintiff has failed to meet this standard with respect to any of Defendants’ “schemes.”

1. The Pricing Scheme and the Distribution Scheme

⁹ Express Scripts does not cite *In re Avandia* in any of its briefing, instead relying on *Maio* and district court decisions issued before *In re Avandia* came down. Express Scripts’ failure to address this clearly relevant Third Circuit precedent is troubling.

Plaintiffs does not identify any specific misrepresentations Defendants made in the course of the “distribution scheme.” Turning to the “pricing scheme,” Plaintiff seems to contend that Mallinckrodt misrepresented Acthar’s AWP to pharmaceutical industry publications relied on by Plaintiff. (FAC at ¶¶ 242–43). However, Plaintiff fails to explain what was misleading about the AWP’s Mallinckrodt reported—after all, the Amended Complaint suggests that the listed AWP was the price actually charged to end payors in the market. (*Id.* at ¶ 209).¹⁰

Plaintiff also points to a number of allegedly false statements Defendants made concerning Acthar’s price. Specifically, it highlights Mallinckrodt CEO Mark Trudeau’s 2018 statements that the price of Acthar was \$36,382, (*id.* at ¶ 233), his later statement that the price was \$38,892, (*id.* at ¶ 238), and Express Scripts Senior Vice President Everett Neville’s 2017 statement that Acthar is overpriced. (*Id.* at ¶ 252). But Plaintiff fails to supply any allegations showing that these statements were false—indeed, by its theory, Everett’s statement was true.¹¹ Consequently, Plaintiff has failed to allege that any aspect of the “distribution scheme” or the “pricing scheme” amounted to wire fraud or mail fraud.

2. The “Marketing Scheme”

In describing the “marketing scheme,” the Amended Complaint lays out various forms of potentially fraudulent activity, including that Mallinckrodt KOLs and MSLs promoted Acthar for off-label uses, that Mallinckrodt offered bribes and kickbacks to doctors in exchange for

¹⁰ Plaintiff relies on *In re Insulin Pricing Litigation*, which found that the artificial inflation of a drug’s AWP by its manufacturer could constitute mail fraud or wire fraud. No. 17-699, 2019 WL 643709, at *5 (D.N.J. Feb. 15, 2019). However, in that case the plaintiffs alleged that the defendant manufacturers were secretly offering substantial discounts to certain distributors, meaning that the published AWP’s were inaccurate. *Id.* at *3. Plaintiff makes no comparable allegation here.

¹¹ Plaintiff alleges that it only paid \$26,100.28 for the dose of Acthar that it purchased in 2018, which does conflict with Trudeau’s representations of Acthar’s price. (*Id.* at ¶ 29). But on each occasion, Trudeau added the caveat that Mallinckrodt offers discounts to payors. (*Id.* at ¶¶ 233, 238). While Plaintiff asserts that this was itself a misrepresentation, as it claims that Mallinckrodt does not offer any discounts to TPPs, (*id.* at ¶ 234), the fact that Plaintiff paid only \$26,100.28 means that it must have received some sort discount, given that Plaintiff repeatedly alleges that Acthar was genuinely priced at over \$40,000 in 2018. (FAC at ¶¶ 37, 232, 234, 553).

prescribing Acthar, and that Mallinckrodt illegally subsidized patient copays through the PAP. Nevertheless, Mallinckrodt and Express Scripts assert that Plaintiff fails to identify any actionable misrepresentations or omissions in connection with this activity, and that to the extent they are identified, these misrepresentations and omissions are not pleaded with the particularity required by Rule 9(b). (Doc. No. 49-2 at 34–35; Doc. No. 50-1 at 44–46).

In its briefing, Plaintiff does not respond to Defendants’ assertions, and the Court is inclined to agree that Plaintiff has failed to satisfy Rule 9(b)’s pleading standard. Plaintiff’s allegations of off-label marketing are mostly vague and conclusory, and even when they are more specific, they fail to establish that the misrepresentations actually resulted in more Acthar prescriptions being written, such as with the allegations concerning the 2013 dinners that Pratta hosted.¹² (FAC at ¶¶ 410–13). Further, Plaintiff offers no explanation as to why Mallinckrodt’s non-disclosure of its payments to KOLs and its role in the PAP amount to actionable omissions. *See Washington Cty. Bd. of Edu. v. Mallinckrodt ARD, Inc.*, 431 F. Supp. 3d 698, 714 (D. Md. 2020) (holding, in an Acthar fraud case with materially similar allegations, that “[t]he PAP may well have violated an antikickback statute . . . but [p]laintiff has not identified a misrepresentation related to the PAP that is actionable”). In light of Plaintiff’s failure to point out which specific aspects of the “marketing scheme” involved mail fraud and wire fraud, the Court must dismiss Plaintiff’s substantive NJ RICO claim.¹³

¹² Plaintiff does provide some more specific allegations concerning Mallinckrodt’s relationship with certain KOLs, but even in these instances it fails to identify what the specific misrepresentations were. For example, Plaintiff alleges that Mallinckrodt provided funding to a Dr. James A. Tumlin to conduct and publish studies on the use of Acthar to treat non-FDA-approved indications, but Plaintiff does not explain what specific false representations Dr. Tumlin may have made. (FAC at ¶¶ 317–33).

¹³ Notably, in *Humana Inc. v. Mallinckrodt ARD LLC*, yet another Acthar antitrust/RICO case, the court found that a TPP had adequately pleaded predicate acts of wire fraud and mail fraud for its federal RICO claim against Mallinckrodt relating to its marketing of Acthar. No. 19-6926, 2020 WL 3041309, at *12 (C.D. Cal. Mar. 9, 2020). Most saliently, the *Humana* plaintiff alleged that: (1) there was a set of doctors who received substantial sums from Mallinckrodt to promote Acthar; (2) these doctors knew that this remuneration violated federal law; and (3) when obtaining authorization to prescribe Acthar from TPPs, including the plaintiff, these doctors affirmatively represented

F. NJ RICO Conspiracy (Count IV)

Plaintiff also alleges that Defendants conspired to violate NJ RICO, triggering liability under N.J.S.A. 2C:41–2(d). However, NJ RICO conspiracy claims “necessarily must fail if the substantive claims are themselves deficient.” *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1191 (3d Cir. 1993); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 529 (D.N.J. 2011). Because Plaintiff has failed to state a claim under Section 2C:41–2(c), its Section 2C:41–2(d) claim also fails.

G. Negligent Misrepresentation (Count V)

“[U]nder New Jersey law negligent misrepresentation requires a showing that defendant negligently provided false information and that plaintiff incurred damages proximately caused by its reliance on that information.” *Highlands Ins. Co. v. Hobbs Grp., LLC*, 373 F.3d 347, 351 (3d Cir. 2004); *see also H. Rosenblum, Inc. v. Adler*, 461 A.2d 138, 142–43 (N.J. 1983) (“An incorrect statement, negligently made and justifiably relied upon, may be the basis for recovery of damages for economic loss or injury sustained as a consequence of that reliance.”), *superseded by statute on other grounds as stated in FINDERNE MGMT. CO. v. BARRETT*, 809 A.2d 857 (N.J. Super. Ct. App. Div. 2002).

In this Count, Plaintiff only seeks to hold Defendants liable for the alleged misrepresentations they made as part of the “pricing scheme.” (FAC at ¶¶ 672–74). But as discussed above, Plaintiff has failed to establish that any of Defendants’ statements concerning the price of Acthar were actually false or misleading. *See City of Rockford*, 360 F. Supp. 3d at 777 (noting that

that they were not violating state or federal law. *Id.*; First Amended Complaint, *Humana Inc. v. Mallinckrodt ARD LLC*, No. 19-6926, at ¶¶ 30, 117–18 (C.D. Cal. Oct. 2, 2019) (Doc. No. 46). Plaintiff’s Amended Complaint hints at similar conduct, but perhaps due to the Amended Complaint’s extreme lack of organization, this theory of misrepresentation never clearly coalesces. If Plaintiff wishes to pursue such a theory, it must attempt to amend its complaint.

“high prices do not in and of themselves constitute false representations”). Thus, Plaintiff’s negligent misrepresentation claim must be dismissed.

H. Civil Conspiracy (Count VI)¹⁴

Under New Jersey law, “[a] civil conspiracy is a combination of two or more persons acting in concert to commit an unlawful act by unlawful means, the principal element of which is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that results in damage.” *Morgan v. Union Cty. Bd. of Chosen Freeholders*, 633 A.2d 985, 998 (N.J. Super. Ct. App. Div. 1993). As such, civil conspiracy claims require both an agreement and “[s]ome act that is itself a tort . . . committed by one of the parties in pursuance of the agreement.” *Morganroth & Morganroth v. Norris, McLaughlin & Marcus, P.C.*, 331 F.3d 406, 414 (3d Cir. 2003) (noting that “[m]ere agreement to do a wrongful act can never alone amount to a tort”).

The torts underlying Plaintiff’s civil conspiracy claim are its NJCFA, NJAA, NJ RICO, and negligent misrepresentation claims. As discussed, only Plaintiff’s NJAA claim against Mallinckrodt is surviving these motions to dismiss. Consequently, Plaintiff has failed to allege that Defendants both agreed to commit a tort and that a tort was actually committed in furtherance of that agreement. Thus, Plaintiff’s civil conspiracy claim must be dismissed.

I. Unjust Enrichment (Count VII)

“To establish unjust enrichment, a plaintiff must show both that defendant received a benefit and that retention of that benefit without payment would be unjust.” *VRG Grp. v. GKN Realty Corp.*, 641 A.2d 519, 526 (N.J. 1994). To state an unjust enrichment claim, the plaintiff must allege that “(1) at plaintiff’s expense (2) defendant received benefit (3) under circumstances

¹⁴ Plaintiff’s Amended Complaint indicates that it is bringing a claim for “conspiracy/aiding and abetting,” but its briefing only discusses conspiracy, rather than the separate claim of aiding in the commission of a tort. (Doc. No. 44 at 37–38; Doc. No. 45 36–37). Therefore, the Court assumes that Plaintiff is only attempting to bring a civil conspiracy claim.

that would make it unjust for defendant to retain benefit without paying for it.” *Gov’t Emp. Insur. Co. v. Ningning He*, No. 19-9465, 2019 WL 5558868, at *5 (D.N.J. Oct. 29, 2019) (internal quotation omitted). Further, “the plaintiff must allege a sufficiently direct relationship with the defendant to support the claim.” *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 711 (D.N.J. 2011).

While Plaintiff insists that it is bringing a quasi-contract unjust enrichment claim, it is plain that Plaintiff’s allegations against Defendants sound in tort. In the tort setting, plaintiffs cannot proceed on an unjust enrichment claim once their traditional tort claims have been dismissed. *Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d 912, 936–37 (3d Cir. 1999).

Because the Court is dismissing all of Plaintiff’s other claims against Express Scripts, it must also dismiss Plaintiff’s unjust enrichment claims against it. However, Plaintiff’s NJAA claim against Mallinckrodt is surviving, and thus so may its unjust enrichment claim. Mallinckrodt’s argument that Plaintiff has failed to allege a sufficiently direct relationship with Mallinckrodt is unpersuasive: Plaintiff has alleged that Mallinckrodt sold Acthar on consignment, retaining title until the time of sale, meaning that Plaintiff was effectively buying directly from Mallinckrodt. Thus, Plaintiff’s unjust enrichment claim against Mallinckrodt remains viable.

V. PRATTA’S MOTION TO DISMISS THE AMENDED COMPLAINT

In addition to Mallinckrodt and Express Scripts, Plaintiff also names Pratta as a defendant in every count of the Amended Complaint. However, Plaintiff’s allegations against Pratta are extremely conclusory; it does little more than allege that Pratta was an employee of Mallinckrodt during the relevant time period, other than to describe two dinners in 2013 where she allegedly misrepresented the efficacy of Acthar. (FAC at ¶¶ 413–14). Plaintiff’s claims against Pratta fail

for the same reasons most of its claims against Mallinckrodt and Express Scripts fail: there are no non-conclusory allegations that Pratta was involved in any anticompetitive activity, nor any particularized allegations that she made any representations that actually inflated Acthar's price. All of Plaintiff's claims against Pratta must be dismissed.

VI. CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Transfer is **DENIED**; Mallinckrodt's Motion to Stay is **DENIED**; Mallinckrodt, Express Scripts, and Pratta's Motions to Dismiss are **DENIED** as moot; the Motions to Strike are **DENIED**; Mallinckrodt's Motion to Dismiss the Amended Complaint is **GRANTED IN PART** and **DENIED IN PART**; and Express Scripts and Pratta's Motions to Dismiss are **GRANTED**.

Dated: 8/18/2020 _____

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge

PROOF OF SERVICE

1. I am over eighteen years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 777 South Figueroa Street, Forty-Fourth Floor, Los Angeles, California 90017-5844.

2. On **August 18, 2020**, I served the following document(s):

THE DEFENDANT MALLINCKRODT ENTITIES' RESPONSE TO PLAINTIFF HCSC'S NOTICE OF SUPPLEMENTAL AUTHORITY RE DEMURRER AND MOTION TO STRIKE

3. I served the document(s) on the following person(s):

[SEE ATTACHED SERVICE LIST]

4. The documents were served by the following means:

☐ **By U.S. Mail.** I enclosed the document(s) in a sealed envelope or package addressed to the person(s) at the address(es) in Item 3 and **(check one)**:

☐ deposited the sealed envelope with the United States Postal Service, with the postage fully prepaid.

☐ placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for mailing. On the same day the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

I am employed in the county where the mailing occurred. The envelope or package was placed in the mail at Los Angeles, California.

☐ **By Overnight Delivery/Express Mail.** I enclosed the documents and an unsigned copy of this declaration in a sealed envelope or package designated by **[name of delivery company or U.S. Postal Service for Express Mail]** addressed to the persons at the address(es) listed in Item 3, with **[Express Mail postage or, if not Express Mail, delivery fees]** prepaid or provided for. I placed the sealed envelope or package for collection and delivery, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for express delivery. On the same day the correspondence is collected for delivery, it is placed for collection in the ordinary course of business in a box regularly maintained by **[name of delivery company or U.S. Postal Service for Express Mail]** or delivered to a courier or driver authorized by **[name of delivery company]** to receive documents.

☐ **By Messenger Service.** I served the documents by placing them in an envelope or package addressed to the persons at the address(es) listed in Item 3 and providing them to a professional messenger service for service. (See attached Declaration(s) of Messenger.)

- ☐ **By Facsimile Transmission.** Based on an agreement between the parties to accept service by facsimile transmission, which was confirmed in writing, I faxed the document(s) and an unsigned copy of this declaration to the person(s) at the facsimile numbers listed in Item 3 on **August 18, 2020**, at [type time]. The transmission was reported as complete without error by a transmission report issued by the facsimile machine that I used immediately following the transmission. A true and correct copy of the facsimile transmission report, which I printed out, is attached hereto.
- ☒ **By Electronic Service (E-mail).** Based on California Rule of Court 2.251(c)(3), or on a court order, or on an agreement of the parties to accept service by electronic transmission, I transmitted the document(s) to the person(s) at the electronic notification address(es) listed in Item 3 on **August 18, 2020**.
- ☐ **Via Court Notice of Electronic Filing.** The document(s) will be served by the court via NEF and hyperlink to the document(s). On **August 18, 2020**, I checked the CM/ECF docket for this case or adversary proceeding and determined that the person(s) listed in Item 3 are on the Electronic Mail Notice List to receive NEF transmission at the email addresses indicated in Item 3 [or on the attached service list, if applicable].
- ☐ **Via Electronic Notification.** The document(s) will be served via electronic notification on **August 18, 2020** on the person(s) listed in Item 3 at the email addresses indicated in Item 3 [or on the attached service list, if applicable].
- ☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.
- ☐ **FEDERAL:** I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Dated: **August 18, 2020**.

Signature: Kathryn Jensen

Type or Print Name: Kathryn Jensen

E-Service Address:

kathryn.jensen@arnoldporter.com

Health Care Service Corp. v. Mallinckrodt ARD LLC, etc., et al.
Alameda Superior Court Case No. RG20056354

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EXHIBIT 55

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Case Management Order

Date: 08/19/2020

Time: 03:00 PM

Dept: 19

Judge: Stephen Kaus

ORDER re: CASE MANAGEMENT

The Court has ordered the following after review of the case without a conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 08/25/2020 at 09:00 AM in Dept. 19.

NOTICES

The Court orders counsel and/or self-represented parties to obtain a copy of this order from the court's website <http://www.alameda.courts.ca.gov/domainweb>.

Any delay in the trial, caused by non-compliance with any order contained herein, shall be the subject of sanctions pursuant to CCP 177.5.

Dated: 08/19/2020

 Facsimile

Judge Stephen Kaus

EXHIBIT 56

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp	No. RG20056354
Plaintiff/Petitioner(s)	
VS.	Minutes
Mallinckrodt ARD LLC	
Defendant/Respondent(s)	
(Abbreviated Title)	

Department 19 Honorable Stephen Kaus , Judge

Cause called for Case Management Conference on August 19, 2020.

Plaintiff Health Care Service Corp not appearing.
Defendant Mallinckrodt ARD LLC not appearing.
Defendant Mallinckrodt PLC not appearing.

ORDER re: CASE MANAGEMENT

The Court has ordered the following after review of the case without a conference.

FURTHER CONFERENCE

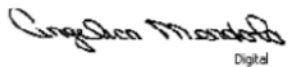
A further Case Management Conference is scheduled for 08/25/2020 at 09:00 AM in Dept. 19.

NOTICES

The Court orders counsel and/or self-represented parties to obtain a copy of this order from the court's website <http://www.alameda.courts.ca.gov/domainweb>.

Minutes of 08/19/2020
Entered on 08/20/2020

Chad Finke Executive Officer / Clerk of the Superior Court

By  Digital

Deputy Clerk

EXHIBIT 57

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp
Plaintiff/Petitioner(s)
VS.
Mallinckrodt ARD LLC
Defendant/Respondent(s)
(Abbreviated Title)

No. RG20056354

Minutes

Department 19

Honorable Stephen Kaus , Judge

Cause called for Motion: August 19, 2020.

With respect to defendants Mallinckrodt Ard LLC's and Mallinckrodt plc's (collectively "Defendant") Demurrer to and Motion to Strike Portions of plaintiff Health Care Service Corp.'s ("Plaintiff") Complaint, the Court **ORDERS THE PARTIES TO APPEAR** for hearing, which will be conducted on Tuesday, August 25, 2020 at 9:00 a.m. in Dept. 19. The hearing will be conducted using the Bluejeans Teleconference Network. Dept. 19 will send invitations to the parties to participate in the hearing via Bluejeans in advance of the 8/25/2020 hearing date.

In order to facilitate the discussion at the 8/25/2020 hearing, the Court provides the following substantive Tentative Ruling on the Demurrer and Motion to Strike.

The Court **SUSTAINS IN PART** and **OVERRULES IN PART** Defendant's Demurrer as set forth below. The Court **DENIES** Defendant's Motion to Strike in its entirety as set forth below.

Plaintiff's Complaint alleges nine Causes of Action based on allegations that it was damaged by Defendants' monopolistic and illegal practices with respect to an adrenocorticotrophic hormone ("ACTH") analogue drug called Acthar, which is used, inter alia, as an anti-inflammatory drug.

FACTS

The Complaint alleges the following relevant facts. Defendant produces H.P. Acthar Gel (Acthar), a drug that was invented in 1948 and first approved by the FDA in 1952. (Complaint ¶¶ 2, 5, 57.) Acthar was approved to treat multiple sclerosis ("MS") in 1979 and to treat infantile spasms in 2010. (Id. ¶¶ 60, 67.) The latter condition is the only one for which Acthar may be considered the most effective "first line" treatment. (Id. at ¶ 67.) Acthar has also been approved for use of idiopathic membranous nephropathy, exacerbations of dermatomyositis (polymyositis), sarcoidosis, and inflammatory eye disease, and as an adjunct therapy to improve effectiveness of primary therapies for psoriatic and rheumatoid arthritis ("RA"). (¶ 64.) As of the filing of the Complaint, Acthar represents 100% of the market for ACTH drugs in the United States. (¶ 183.)

Plaintiff is the nation's largest customer-owned insurer, is an independent licensee of Blue Cross and Blue Shield Association ("BCBSA"), and has an exclusive license to offer BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma and Texas. Plaintiff through its operating divisions and subsidiaries provides Medicare benefits through contracts with the Centers for Medicare and Medicaid Services, provides benefits under various states' Medicaid programs; and private commercial health insurance benefits. Many of the plans operated by Plaintiff offer prescription drug coverage under which claims for Acthar were submitted and paid by Plaintiff. Plaintiff seeks to recover pursuant to those paid claims. (Id., ¶¶ 17-19.)

Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. (Id. ¶¶ 5, 56.) As a result of the later development of synthetic steroid drugs and non-steroidal anti-inflammatory drugs, by the 1990's only a few key uses, such as for treating infantile spasms, remained for Acthar; and the drug

became unprofitable at its then price for then manufacturer Aventis Pharmaceuticals. (¶¶ 6-7.) In 2001, Aventis sold Acthar's rights to Defendant's predecessor Questcor for \$100,000. Questcor raised the price of Acthar from \$40 per unit to \$750 per unit immediately after purchase, to \$1,650 per unit by 2007, at which time the price was raised to \$23,269 per unit. As of 2018, the price had further increased to \$38,892 per unit, such that a single three-unit course of treatment costs nearly \$120,000. (¶¶ 7-8.) Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from just under \$50 million in 2011 to \$636 million in 2016. (¶¶ 72-73.)

Plaintiff alleges that it has paid more than \$100 million for Acthar "during the relevant period," later apparently defined as from 2011 through the present. (¶¶ 85, 200.) Defendant merged with Questcor in August 2014. (¶ 9.)

In June 2007, Defendant "vertically integrated" its sales by distributing Acthar exclusively through the specialty pharmacy CuraScript, "a subsidiary of Express Scripts. CuraScript "is paid a fixed fee for each vial of Acthar" and has the right to return to Defendant any inventory "which goes unsold before its expiration date. (¶¶ 76-84.)

The Complaint alleges that starting in 2010, Defendant established a number of non-profit funds designed to provide assistance to consumers prescribed Acthar to make co-payments required under their health care plans. Defendant set up funds to pay for medications used to treat MS, lupis and RA, which illegally reimbursed co-pays solely for prescriptions of Acthar through 2014. (¶¶ 89-119.) The Complaint alleges on information and belief that Defendant continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 through the present. (¶ 120.)

The Complaint alleges that Defendant began to actively promote off-label uses of Acthar in order to increase sales of the drug. Questcor marketed the drug to focus on "patient types" including those who had had adverse reactions or tolerability problems with IV steroids, even though "common adverse reactions for [Acthar] are similar to those of corticosteroids," which are much less expensive. (¶¶ 121-129.) Questcor's written marketing materials created a false impression that Acthar was better tolerated than steroids. (¶¶ 131-133.) Further, Questcor promoted the so-called "Brod Protocol" requiring a shorter five-day, one vial regimen for Acthar even though there were no peer-reviewed studies showing that Acthar was as effective as less costly alternative drug regimens. Even though this was an admitted off-schedule use of Acthar, Questcor sales representatives routinely told doctors that they should prescribe the five-day regimen and prepared prescription forms with the five-day dosing regimen already written in. (¶¶ 134-145.)

The Complaint further alleges that Defendant paid "kick-backs" to doctors who prescribed Acthar. Defendant did so through a paid speaker program, whereby doctor participants could receive \$2,000 per presentation and up to \$6,000 a day. This was at the high end of industry standard, but a speaking engagement could be to as few as three people who need not be physicians. Approximately, 90% of all Acthar prescriptions are written by approved speakers. Between 2013 and 2016, Defendant paid doctors nearly \$27.5 million in Acthar related payments. (¶¶ 149-156.) A 2018 study published in JAMA Network Open, which appears to use 2015 data, concludes that "aggressive sales tactics and payments from [Defendant] may influence prescribing behavior for [Acthar]." (¶ 158.) Nine doctors who prescribed between \$567,000 and \$3.05 million in Acthar received payments between \$44,000 and \$480,000, although the amounts prescribed by and the amounts paid to each such doctor are not directly proportional. (¶ 159.)

Synacthen is a synthetic ACTH drug approved for sale outside of the United States, where it is used for the same purposes as Acthar. (¶ 162.) In late 2011, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Three other companies engaged in several rounds of negotiations with Novartis with the intent to develop and use Syacthen to compete with Acthar at a lower price. (¶¶ 164-166.) Questcor had "inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer." Yet, Questcor's June 2013 bid, at a minimum of \$135 million, was several multiples higher than the other three bidders, who all submitted comparable offers in terms of value and structure. (¶¶ 168-169.) However, neither Questcor nor Defendant "made more than superficial efforts to pursue commercialization of Synacthen ... to protect Acthar monopoly pricing." (¶ 172.) 14 months after Questcor purchased the rights to Synacthen, Defendant acquired Questcor for \$5.6 billion, an amount almost entirely attributable to the value of Acthar. (¶ 171.) In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen in the United States. (¶ 176.)

DEMURRER STANDARDS

"A demurrer tests the legal sufficiency of the factual allegations in a complaint." (Redfearn v. Trader Joe's Co. (2018) 20 Cal. App. 5th 989, 996.) "As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are deemed to be true, however improbable they may be," unless the "complaint contains allegations of fact inconsistent with attached documents, or allegations contrary to facts which are judicially noticed." (Del E. Webb Corp. v. Structural Materials Co. (1981) 123 Cal. App. 3d 593, 604.) Courts "construe the complaint 'liberally ... with a view to substantial justice between the parties[.]'" (Goncharov v. Uber Techs., Inc. (2018) 19 Cal. App. 5th 1157, 1165.)

"[I]f a plaintiff pleads a claim that fails to state a cause of action, a demurrer is properly sustained[.]" (Boxer v. City of Beverly Hills (2016) 246 Cal. App. 4th 1212, 1225.) "Where the complaint is defective, ... great liberality should be exercised in permitting a plaintiff to amend [the] complaint." (Redfearn, 20 Cal. App. 5th at 996.) "[L]eave to amend should not be granted where ... amendment would be futile." (Id. at 997.)

ANALYSIS OF DEMURRER

The Complaint alleges nine causes of action: (1) Violation of New Jersey RICO Statute (N.J.S.A. § 2C:41-2(c)); (2) Conspiracy to violate New Jersey RICO (N.J.S.A. § 2C:41-2(d)); (3) Monopolization under State Law, inter alia, Bus. & Prof. ("B&P") Code § 17200 et seq. and CA common law (and for violations of statute for 27 other states and territories); (4) Contract or Conspiracy in Restraint of Trade Under State Laws, inter alia, B&P Code §§ 17200 et seq., 16700 et seq., 16720 et seq., and 16750(a) (and the laws of 30 other states); (5) Unfair and Deceptive Practices under State Laws, inter alia, B&P Code § 17200 et seq. (and the laws of 33 other states); (6) fraud; (7) Insurance Fraud under State Law, inter alia, Cal. Ins. Code § 1871 et seq. (and the laws of 39 other states); (8) Tortious Interference with Contractual Relations; and (9) Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer with respect to the Complaint's Counts 1, 2 (New Jersey RICO violations), 5 (Unfair and Deceptive Practices), 6 (Fraud), 7 (Insurance Fraud), and 9 (Unjust Enrichment). The Court **SUSTAINS WITH LEAVE TO AMEND** Defendant's Demurrer to the Complaint's Counts 3 (Monopolization), 4 (Contract or Conspiracy in Restraint of Trade) and 8 (Tortious Interference with Contractual Relations).

1. Demurrer to Complaint Counts 1 and 2 (New Jersey RICO Violations).

Plaintiff's First two Causes of Actions/Counts are brought under New Jersey's "Little RICO" statute at N.J.S.A. § 2C:41-2(c) and (d). N.J.S.A. § 2C:41-2(c) and (d) provide:

"c. It shall be unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

d. It shall be unlawful for any person to conspire as defined by N.J.S. 2C:5-2, to violate any of the provisions of this section."

§ 2C:5-2 is a statute which defines conspiracy under New Jersey law.

In interpreting New Jersey "Little RICO" statute, it is appropriate to seek guidance from federal decisions construing federal RICO provisions, since New Jersey statute borrows its structure, purpose and remedies from federal legislation. (State v. Ball (1993) 268 N.J.Super. 72, 98, affirmed at 141 N.J. 142; Maxim Sewerage Corp. v. Monmouth Ridings (1993) 273 N.J.Super. 84 (although New Jersey RICO statute is broader in application than federal RICO statute, New Jersey will still look to federal case law interpreting RICO to interpret same offense).)

To state a federal RICO claim, a plaintiff must allege "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." (Odom v. Microsoft Corp., 486 F.3d 541, 547 (9th Cir. 2007) (quoting Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985)). "[T]he conduct must be (5) the proximate cause of harm to the victim." (Eclectic Properties E., LLC v. Marcus & Millichap Co., 751 F.3d 990, 997 (9th Cir. 2014).) Racketeering activity "encompass dozens of state and federal offenses, known in RICO parlance as predicates." (RJR Nabisco, Inc. v. European Cmty., 136 S. Ct. 2090, 2096 (2016).) There is a pattern of racketeering activity where there is "a series of related predicates that together demonstrate the existence or threat of continued criminal activity." (Id. at 2096-97.) "[F]ailure to adequately plead a substantive violation of RICO precludes a claim for conspiracy." (Howard v. Am. Online Inc., 208 F.3d 741, 751 (9th Cir. 2000).)

Plaintiff alleges the "Acthar Enterprise," consisting of Defendant, Express Scripts (and its subsidiaries), the Chronic Disease Fund ("CDF"), and the prescribing doctors, was "used as a tool to effectuate a pattern of racketeering activity." (Complaint ¶ 218.) Specifically, Defendant 1) made allegedly false statements, including that Defendant was in compliance with the laws, which constituted mail and wire fraud, as well as use of interstate facilities to conduct unlawful activity, and 2) subsidized co-pays through CDF and made payments to the prescribing doctors which "violated state commercial bribery statutes." (Id. ¶¶ 219-227, 149-159.)

In its Demurrer papers, Defendant does not directly attack the allegations of Counts 1 and 2 of Plaintiff's Complaint. Instead, Defendant contends that none the underlying alleged unlawful conduct set forth in the Complaint -- namely (1) Defendant's "vertical integration" of distribution of Acthar, (2) Defendant's use of a charity to fund patient co-pays solely for use of Acthar, (3) Defendant's active, "improper or false" marketing of Acthar for off-label uses, (4) alleged "kickbacks" to doctors who regularly prescribe Acthar, and (5) purchasing the rights to Acthar's only potential competitor Synacthan in order to prevent Synacthen from entering the United States market -- state actionable conduct against Defendant. (See Moving MPA at pp. 17:20-21:28, 24:25-33:18.) Defendant also contends that Plaintiff's claims are time-barred by the applicable statutes of limitations. (Id. at pp. 22:1-24:4.)

The Court is not persuaded by either of Defendant's arguments. First, with respect to Defendant's argument that the applicable statutes of limitations have run because Plaintiff had notice of at least some of Defendant's alleged wrongful conduct going back to late 2013 (See Exhs. B-D to Defendant's Request for Judicial Notice in Support of Demurrer and Motion to Strike ("RJN")), the Complaint alleges at ¶¶ 177 and 180 that Defendant actively concealed the existence of its illegal scheme and the acts underlying it through false or misleading statements to Plaintiff and the public and that as a result of this "fraudulent concealment," HCSC could not have discovered and remained unaware of Defendant's wrongful conduct until the Federal Trade Commission and the U.S. Dept. of Justice brought this conduct to light through investigations, legal actions and/or settlements." Further, ¶ 181 alleges continuing injury to Plaintiff. The Court in considering a Demurrer must accept these allegations as true, no matter how unlikely, unless matters of which the Court may take judicial notice refute Plaintiff's allegations as a matter of law.

Although the late 2013 news articles published in Barron's and the New York Times are evidence tending to show that information regarding Defendant's allegedly improper relationship with CDF was readily available to Plaintiff, they do not as a matter of law establish that Plaintiff had constructive knowledge in 2013 or 2014 of the full extent of Defendant's "racketeering activities" alleged in the Complaint or even that Plaintiff had constructive knowledge of the alleged fraudulent relationship between Defendant and CDF. (See *Richtek USA, Inc. v. uPI Semiconductor Corp.* (2015) 242 Cal.App.4th 651, 660 ("When judicial notice is taken of a document, however, the truthfulness and proper interpretation of the document are disputable."))

Second, the Court finds that Plaintiff has sufficiently alleged a pattern of racketeering activity by Defendant. Plaintiff alleges that Defendant set up a distribution system, which through a subsidiary of Express Scripts, UBC, designed to facilitate and increase sales and prescriptions of Acthar by "interacting directly with patients and third-party payors by coordinating various patient assistance programs, including the ASAP and PAP programs described further below." (¶ 80.) The Complaint alleges that Defendant set up through CDF co-pay charities the sole purpose of which was to eliminate or substantially reduce (see ¶ 112) co-pays for Acthar to patients, so that patients and their doctors would have no incentive to request alternative, more cost-effective drugs, while leaving insurers like Plaintiff to pay their full portion of the allegedly exorbitant price of Acthar. (¶¶ 89-120.) The Complaint contains numerous, specific factual allegations regarding the degree to which Defendant intentionally and directly worked to connect patients with co-pay assistance funded by Defendant. (Ibid., see particularly ¶¶ 106, 112 alleging that Defendant "implemented an "automatic offering" of co-pay assistance to all patients with co-pays greater than \$150, administered by UBC through [Defendant's] reimbursement hub [ASAP]. The ASAP program referred over 98% of the patients who received subsidies" from three Acthar funds operated by CDF.")

The Complaint further alleges that Defendants actively marketed off-label uses and unapproved dosing regimens to increase demand for Acthar, to make use of Acthar seem more price competitive and also to support misleading representations in marketing materials and by salespersons that Acthar was better tolerated than alternative medications, even though the off-label uses and unapproved dosing regimens were not supported by peer-reviewed studies showing Acthar to be as effective as less-costly alternatives. In fact, the Complaint alleges that Defendant's salespeople pre-filled insurance and prescription forms calling for an unvetted five-day dosing regimen referred to as the "Brod Protocol," so that doctors and other health care providers could more readily prescribe this unapproved dosing regimen. (¶¶ 121-146.)

The Complaint also alleges with respect to payments made by Defendants to doctors that in 2007, Defendant "knew that it might have priced itself out of the MS market;" Defendant "heavily marketed" Acthar to doctors who treated conditions such as MS, RA, and sarcoidosis; "Acthar had not been prescribed in large quantities for these conditions" prior to 2014; in 2014, Defendant's president told investors about "a strategy to expand Acthar's sales to patients" with these and other conditions even though "there were no new medical studies suggesting Acthar was needed to treat any of these conditions;" today, "fewer than 10% of Acthar's sales come from prescriptions for infantile spasms," the main use for which Acthar is a primary treatment; and 88% of doctors who submitted more than 10 claims for Acthar received payment from Defendant, while only 35% of all specialists "receive payments from the pharmaceutical industry." (¶¶ 89, 147-159.)

Finally, the Complaint alleges that Defendant "directly misrepresented to [Plaintiff] that it was complying with state and federal law, including laws related to bribery, kickbacks, and false claims" when Defendant submitted data for Prescription Drug Event (PDE) claims "certifying that such data is true, accurate, and complete." (¶¶ 34-39, 177-178, 200, 259, 267-270.) The Complaint also alleges that Defendant's misrepresentations were part of a fraudulent scheme to increase sales of Acthar and that Plaintiff was damaged thereby. (¶¶ 219, 224, 226-228.)

The Court finds that Counts 1 and 2 of the Complaint adequately state New Jersey RICO violation causes of action. Wherefore, the Court OVERRULES Defendant's Demurrer to Counts 1 and 2 of the Complaint.

2. Demurrer to Complaint Counts 5, 6, 7 and 9 for, respectively, State Law Unfair and Deceptive Practices, Fraud, State Law Insurance Fraud, and Unjust Enrichment.

The Court OVERRULES Defendant's Demurrer to the Complaint's Fifth, Sixth, Seventh and Ninth Counts. Defendant's Demurrer MPA does not directly address each of these causes of action. Because the Court has found that Plaintiff has successfully alleged New Jersey "Little RICO" causes of action, the predicates for which involve unfair or deceptive business practices, fraud and insurance fraud, resulting in unjust enrichment to Defendant at Plaintiff's expense, the Court OVERRULES the Demurrer to these Counts.

3. Demurrer to Complaint Counts 3 and 4 for, respectively, Monopolization in Violation of State Laws and Contract or Conspiracy in Restraint of Trade in violation of State Law.

The Complaint's Third and Fourth Counts allege solely Defendant's purchase of the U.S. rights to the drug Synacthen from Novartis for the alleged monopolistic purpose of preventing Synacthen from ever competing with Acthar in the United States as the basis for these causes of action. Defendant contends in its MPA that the Complaint fails to allege the relevant Antitrust Market in which Acthar competes and also that the Complaint fails to allege that Plaintiff has been injured as a result of Defendant's alleged monopolistic actions. (See Moving MPA at pp. 30:1-33:18.)

The Court finds that Defendant's latter argument has more merit than the former. The Complaint alleges facts throughout that undercut Plaintiff's allegation that there is an "ACTH" market of which Acthar is the only current market participant for what Plaintiff has alleged are the off-label uses that now make up the majority of Acthar's sales. (Compare ¶¶ 182-199 with ¶¶ 6, 89, 147-148.) However, ¶¶ 185-186 of the Complaint can be read to identify a small ACTH Market with respect to treatment of infantile spasms and acute exacerbations of MS, for which Synacthen could be the only meaningful competitor to Acthar.

Defendant's argument that the Complaint fails to state facts establishing that Plaintiff has actually suffered damages has greater merit. Based on the facts alleged in the Complaint, Plaintiff is essentially alleging that for a period four years and one month between June 2013 (when Defendant purchased the U.S. rights to Synacthen from Novartis) until July 2017 (when Defendant, as part of a settlement with the FTC, sub-licensed the U.S. rights to Synacthen to West Therapeutic Development, LLC ("West") with the FTC's approval), Defendant wrongfully delayed development of Synacthen as an FDA-approved drug marketable in the U.S. (¶¶ 162-176.) Thus, Plaintiff's alleged damages for Defendant's alleged wrongfully conduct can only be the difference between what Plaintiff paid for Acthar and what it would have paid for lower-cost Synacthen during the roughly 4.1 year period when Synacthen would have been on the U.S. market but for Defendant's monopolistic practices.

Moreover, based on the allegations of the Complaint, the only reasonable inference the Court can draw is that since July 2017, West has been working diligently and in good faith to secure FDA approval of Synacthen in the United States. There are also no facts alleged in the Complaint tending to show that, but

for Defendant's wrongful conduct, Defendant could have secured FDA approval for Synacthen in a shorter period from its June 2013 purchase date than it will take West to secure FDA approval from West's July 2017 purchase date.

However, the Complaint filed on 2/27/2020 alleges neither that West has already secured FDA approval of Synacthen nor alleged any reasonable estimate regarding when the FDA will approve Synacthen or when Synacthen will actually be available for purchase in the U.S. As such, Plaintiff's claim for damages at present appears to be entirely speculative and hypothetical. For example, if it takes West ten years from purchase to bring Synacthen to the U.S. market, then a finder of fact could reasonably infer that it would have taken Defendant acting in good faith ten years from purchase to bring Synacthen to the U.S. market. If that were the case, Plaintiff would have no damages until the 4.1 year period between June 2023 and July 2027, when but for Defendant's alleged wrongful conduct Plaintiff would have been able to save money by purchasing Synacthen instead of Acthar.

"If the existence-and not the amount-of damages alleged in a fraud pleading is 'too remote, speculative or uncertain,' then the pleading cannot state a claim for relief." (Beckwith v. Dahl (2012) 205 Cal.App.4th 1039, 1064, citing Block v. Tobin (1975) 45 Cal.App.3d 214, 219.) As with fraud claims, "California requires a 'high degree of particularity' in the pleading" antitrust violations. (Freeman v. San Diego Ass'n of Realtors (1999) 77 Cal.App.4th 171, 196.)

In Opposition Plaintiff argues that the federal district court case Tawfilis v. Allergan, Inc. (C.D. Cal. 2015) 157 F.Supp.3d 853 supports a finding that Plaintiff has adequately alleged damages based solely on Defendant's alleged wrongful conduct regarding Synacthen. However, Tawfilis is distinguishable. While the underlying facts and claims of the dispute in Tawfilis are similar to the present action, the Tawfilis complaint contained much more detailed allegations than Plaintiff's Complaint does about the steps the potential competitor had taken so that its product Innotox could compete with defendant's Botox in the U.S. market, before the defendant purchased the U.S. rights to Innotox from its potential competitor. The additional alleged facts included the dates on which the competitor applied for and obtained U.S. patents, its plan to build a new manufacturing facility between the first quarter of 2012 and the first quarter of 2013 in order to increase production of Innotox for the entry into the U.S. market, and, most importantly, that Innotox "could have been approved for sale in the U.S. in less than two years following its obtaining regulatory approval abroad in mid-2013." (157 F.Supp.3d at 857.) Based on these allegations, plaintiff Tawfilis could allege in his complaint actual damages at least by the time of trial, in light of the 10/20/2015 date on which the federal court's ruling on defendant's Motion to Dismiss entered. In contrast, Plaintiff's Complaint contains no allegations regarding what West has done to obtain FDA approval for Synacthen or when Synacthen might reasonably be available for purchase in the United States.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaints Third and Fourth Counts WITH LEAVE TO AMEND.

4. Demurrer to Complaint Count 8 for Tortious Interference with Contractual Relations.

The Complaint's Eighth Cause of Action appears to be an attempt to allege a cause of action for inducing breach of contract. (See CACI Jury Instruction No. 2200.) The elements of such a cause of action are: (1) the existence of a contract between plaintiff and a third party; (2) that defendant knew of the contract; (3) that defendant's conduct caused the third party to breach the contract; (4) plaintiff was harmed; and (5) defendant's conduct was a substantial factor in causing plaintiff's harm. (Ibid; Pacific Gas & Electric Co. v. Bear Stearns & Co. (1990) 50 Cal.3d 1118, 1126.) The Court notes that CACI No. 2021 contains a separate jury instruction for "Intentional Interference with Contractual Relations" where plaintiff must show only that, inter alia, defendant's conduct "made performance [of the third party contract] more expensive or difficult." (PG&E, supra, 50 Cal.3d at 1129.)

As a cause of action for inducing breach of contract, the Eighth Cause of Action fails because this court agrees with the reasoning of the Court in Humana v. Mallinkrodt Ard LLC (C.D. Cal. 2020) 2020 WL 3041308 at p. *15, that patients' acceptances of co-pay assistance from a patient assistance program ("PAP"), even if the PAP does not comply with fraud and abuse laws, is not a breach of an insurance agreement that requires members to pay their share of costs for prescription drugs. (See RJN, Exh. A at p. 10.)

In Opposition, Plaintiff contends the 2005 Dept. Health and Human Services Office of Inspector General ("OIG") Bulletin published in the Federal Register relied upon by Defendant and the Humana Court only applies to Medicare Part D beneficiaries and does not apply to non-Medicare Part D beneficiaries who are some of Plaintiff's members. However, this Court considers the OIG guidance evidence of a public policy applicable to all health insurance contracts intended to enable patients with modest incomes to have access

to medications, particularly where patients are unlikely to have any personal knowledge whether charity funds like those alleged to have been set up by Defendant do or do not follow legal requirements. Plaintiff specifically alleges that Defendant kept the fraudulent nature of its charities a secret for years. (§§ 177-180.) Where Plaintiff expressly alleges that it, a large and sophisticated player in the health care and medications markets "with more than 16 million members" (§ 17), could not figure out what Defendant was allegedly up to until federal agencies became involved (§ 180), this Court will not impose greater knowledge requirements or duties to investigate on patients.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaint's Count 8 WITH LEAVE TO AMEND. In an amended pleading, Plaintiff may seek to state a cause of action under either of CACI Nos. 2200 or 2201.

MOTION TO STRIKE

MOTION TO STRIKE STANDARDS

"The court may, upon a motion . . . or at any time in its discretion, and upon terms it deems proper: (a) [s]trike out any irrelevant, false, or improper matter inserted in any pleading[;] . . . [and/or] (b) [s]trike out all or any part of any pleading not drawn or filed in conformity with the laws of this state, a court rule, or an order of the court." (CCP § 436.) An "irrelevant matter," or "immaterial allegation," means: (1) an allegation that is not essential to the statement of a claim or defense; (2) an allegation that is neither pertinent to nor supported by an otherwise sufficient claim or defense; or (3) a demand for judgment requesting relief not supported by the allegations of the complaint or cross-complaint. (CCP § 431.10(b).)

ANALYSIS OF DEFENDANT'S MOTION TO STRIKE

The Court DENIES Defendant's Motion to Strike §§ 76-85 regarding Defendant's "vertical integration" of distribution of Acthar. The Court is not persuaded by Plaintiff's arguments that Defendant's actions to limit distribution to a single distributor, Express Scripts, artificially maintained the price of Acthar because it prevented multiple distributors from negotiating to lower prices, because Defendant was still the only producer of Acthar and could thereby set whatever price it wished regardless of the number of distributors in dealt with. Nevertheless, these paragraphs are relevant to the Complaint as a whole because, for example, they allege that the "integrated services [were] critical to the scheme" (§ 78) because they enabled Defendant to funnel patients using Acthar into Defendant's fraudulent ASAP and PAPs. (§§ 80-84.) Further, § 85 contains allegations relevant to Plaintiff's damages claims.

The Court DENIES Defendant's Motion to Strike §§ 89-120. The Court has found that these paragraphs allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 223 at p. 43:5-6. Defendant does not properly identify the portion § 223 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, while the Court agrees with Defendant and the Humana Court at p. * 13 that co-pay assistance paid by a PAP to patient does not constitute a commercial bribe, the Complaint also alleges Defendant paid "bribes" and "kickbacks" to doctors to prescribe Acthar. N.J.S.A. § 2C:21-10 specifically references a "physician" as a person with a "duty of fidelity" to whom a bribe might be given as consideration for knowing violation of said duty of fidelity.

The Court DENIES Defendant's Motion to Strike §§ 273-275. The Court has found above that the allegations underlying the allegations in these paragraphs are sufficient to allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 281 at p. 56:22. Defendant does not properly identify the portion § 281 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, The Court has found above that the allegations underlying the relevant allegation in these paragraph are sufficient to allege actionable conduct against Defendant.

The Court DENIES Defendant's Motion to Strike §§ 14, 149-161, 259, 272-273. The Court has found above that these allegations are sufficient to state actionable conduct against defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike "§ 181, Ins. 21-22." The Complaint contains no matter meeting this description. (See also CRC Rule 3.1322(a).)

The Court DENIES Defendant's Motion to Strike §§ 13, 121-148. The allegations are relevant to

Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike ¶¶ 15, 162-176, 244-247, 249-253. Plaintiff's allegations regarding Defendant's alleged efforts to prevent competitor drug Synacthen from the U.S. market are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike ¶ 200. Defendant's Notice appears to seek to strike only a portion of ¶ 200, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike ¶ 203. Defendant's Notice appears to seek to strike only a portion of ¶ 203, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike ¶¶ 161 and 175. While Defendant's settlement of legal claims brought by the U.S. Justice Dept. and the FTC are not admissible as evidence of wrongful conduct, the allegations could be relevant as evidence regarding when Plaintiff allegedly learned or was put on notice of Defendant's wrongful conduct.

The Court DENIES Defendant's Motion to Strike ¶¶ 245, 253, 257 and 280. This trial Court does not have the resources to examine each of the 133 referenced statutes from approximately 40 different jurisdictions, which "the Court determines to be subject to a legal bar." The Court notes that it authorized, and Defendant filed, a 25-page moving MPA and a 15-page Reply Brief. The Court will not address issues not properly raised in the substantial briefing.

With respect to Defendants' Request for Judicial Notice ("RJN") Exhs. A-I, the Court GRANTS judicial notice of the existence of the documents but does not take judicial notice of the truth of the matters stated therein. (See *Licudine v. Cedars-Sinai Med. Ctr.* (2016) 3 Cal.App.5th 881, 902, quoting *In re Joseph H.* (2015) 237 Cal.App.4th 517, 541-542 ("[w]e can take judicial notice of official acts and public records, but we cannot take judicial notice of the truth of the matters stated therein.") The Court GRANTS Defendants' RJN with respect to Exh. J. The Court GRANTS Defendants' RJN with respect to Exhs. K-O only with respect to the non-California legal authorities stated therein; the Court does not take judicial notice of the statements that appear to be legal argument regarding the interpretation of those non-California legal authorities.

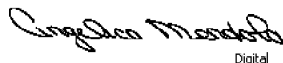
The Court GRANTS Plaintiff's RJN with respect to Exh. 1 to the Opp. Weiler Dec. The Court GRANTS Plaintiff's RJN with respect to the existence of Exhs. 2 and 3 to the Opp. Weiler Dec. but does not take judicial notice of the truth of the facts asserted therein.

Minutes of 08/19/2020

Entered on 08/20/2020

Chad Finke Executive Officer / Clerk of the Superior Court

By



Digital

Deputy Clerk

EXHIBIT 58

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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Order

Demurrer to Complaint

The Demurrer to Complaint was set for hearing on 08/19/2020 at 03:00 PM in Department 19 before the Honorable Stephen Kaus. The Tentative Ruling was published and was contested.

IT IS HEREBY ORDERED THAT:

With respect to defendants Mallinckrodt Ard LLC's and Mallinckrodt plc's (collectively "Defendant") Demurrer to and Motion to Strike Portions of plaintiff Health Care Service Corp.'s ("Plaintiff") Complaint, the Court **ORDERS THE PARTIES TO APPEAR** for hearing, which will be conducted on Tuesday, August 25, 2020 at 9:00 a.m. in Dept. 19. The hearing will be conducted using the Bluejeans Teleconference Network. Dept. 19 will send invitations to the parties to participate in the hearing via Bluejeans in advance of the 8/25/2020 hearing date.

In order to facilitate the discussion at the 8/25/2020 hearing, the Court provides the following substantive Tentative Ruling on the Demurrer and Motion to Strike.

The Court **SUSTAINS IN PART** and **OVERRULES IN PART** Defendant's Demurrer as set forth below. The Court **DENIES** Defendant's Motion to Strike in its entirety as set forth below.

Plaintiff's Complaint alleges nine Causes of Action based on allegations that it was damaged by Defendants' monopolistic and illegal practices with respect to an adrenocorticotrophic hormone ("ACTH") analogue drug called Acthar, which is used, inter alia, as an anti-inflammatory drug.

FACTS

The Complaint alleges the following relevant facts. Defendant produces H.P. Acthar Gel (Acthar), a drug that was invented in 1948 and first approved by the FDA in 1952. (Complaint ¶¶ 2, 5, 57.) Acthar was approved to treat multiple sclerosis ("MS") in 1979 and to treat infantile spasms in 2010. (Id. ¶¶ 60, 67.) The latter condition is the only one for which Acthar may be considered the most effective "first line" treatment. (Id. at ¶ 67.) Acthar has also been approved for use of idiopathic membranous nephropathy, exacerbations of dermatomyositis (polymyositis), sarcoidosis, and inflammatory eye disease, and as an adjunct therapy to improve effectiveness of primary therapies for psoriatic and rheumatoid arthritis ("RA"). (¶ 64.) As of the filing of the Complaint, Acthar represents 100% of the market for ACTH drugs in the United States. (¶ 183.)

Plaintiff is the nation's largest customer-owned insurer, is an independent licensee of Blue Cross and

Order

Blue Shield Association ("BCBSA"), and has an exclusive license to offer BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma and Texas. Plaintiff through its operating divisions and subsidiaries provides Medicare benefits through contracts with the Centers for Medicare and Medicaid Services, provides benefits under various states' Medicaid programs; and private commercial health insurance benefits. Many of the plans operated by Plaintiff offer prescription drug coverage under which claims for Acthar were submitted and paid by Plaintiff. Plaintiff seeks to recover pursuant to those paid claims. (Id., ¶¶ 17-19.)

Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. (Id. ¶¶ 5, 56.) As a result of the later development of synthetic steroid drugs and non-steroidal anti-inflammatory drugs, by the 1990's only a few key uses, such as for treating infantile spasms, remained for Acthar; and the drug became unprofitable at its then price for then manufacturer Aventis Pharmaceuticals. (¶¶ 6-7.) In 2001, Aventis sold Acthar's rights to Defendant's predecessor Questcor for \$100,000. Questcor raised the price of Acthar from \$40 per unit to \$750 per unit immediately after purchase, to \$1,650 per unit by 2007, at which time the price was raised to \$23,269 per unit. As of 2018, the price had further increased to \$38,892 per unit, such that a single three-unit course of treatment costs nearly \$120,000. (¶¶ 7-8.) Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from just under \$50 million in 2011 to \$636 million in 2016. (¶¶ 72-73.)

Plaintiff alleges that it has paid more than \$100 million for Acthar "during the relevant period," later apparently defined as from 2011 through the present. (¶¶ 85, 200.) Defendant merged with Questcor in August 2014. (¶ 9.)

In June 2007, Defendant "vertically integrated" its sales by distributing Acthar exclusively through the specialty pharmacy CuraScript, "a subsidiary of Express Scripts. CuraScript "is paid a fixed fee for each vial of Acthar" and has the right to return to Defendant any inventory "which goes unsold before its expiration date. (¶¶ 76-84.)

The Complaint alleges that starting in 2010, Defendant established a number of non-profit funds designed to provide assistance to consumers prescribed Acthar to make co-payments required under their health care plans. Defendant set up funds to pay for medications used to treat MS, lupis and RA, which illegally reimbursed co-pays solely for prescriptions of Acthar through 2014. (¶¶ 89-119.) The Complaint alleges on information and belief that Defendant continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 through the present. (¶ 120.)

The Complaint alleges that Defendant began to actively promote off-label uses of Acthar in order to increase sales of the drug. Questcor marketed the drug to focus on "patient types" including those who had had adverse reactions or tolerability problems with IV steroids, even though "common adverse reactions for [Acthar] are similar to those of corticosteroids," which are much less expensive. (¶¶ 121-129.) Questcor's written marketing materials created a false impression that Acthar was better tolerated than steroids. (¶¶ 131-133.) Further, Questcor promoted the so-called "Brod Protocol" requiring a shorter five-day, one vial regimen for Acthar even though there were no peer-reviewed studies showing that Acthar was as effective as less costly alternative drug regimens. Even though this was an admitted off-schedule use of Acthar, Questcor sales representatives routinely told doctors that they should prescribe the five-day regimen and prepared prescription forms with the five-day dosing regimen already written in. (¶¶ 134-145.)

The Complaint further alleges that Defendant paid "kick-backs" to doctors who prescribed Acthar. Defendant did so through a paid speaker program, whereby doctor participants could receive \$2,000 per presentation and up to \$6,000 a day. This was at the high end of industry standard, but a speaking engagement could be to as few as three people who need not be physicians. Approximately, 90% of all Acthar prescriptions are written by approved speakers. Between 2013 and 2016, Defendant paid doctors nearly \$27.5 million in Acthar related payments. (¶¶ 149-156.) A 2018 study published in JAMA Network Open, which appears to use 2015 data, concludes that "aggressive sales tactics and payments from [Defendant] may influence prescribing behavior for [Acthar]." (¶ 158.) Nine doctors who prescribed between \$567,000 and \$3.05 million in Acthar received payments between \$44,000 and \$480,000, although the amounts prescribed by and the amounts paid to each such doctor are not directly proportional. (¶ 159.)

Synacthen is a synthetic ACTH drug approved for sale outside of the United States, where it is used for

the same purposes as Acthar. (§ 162.) In late 2011, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Three other companies engaged in several rounds of negotiations with Novartis with the intent to develop and use Synacthen to compete with Acthar at a lower price. (§§ 164-166.) Questcor had "inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer." Yet, Questcor's June 2013 bid, at a minimum of \$135 million, was several multiples higher than the other three bidders, who all submitted comparable offers in terms of value and structure. (§§ 168-169.) However, neither Questcor nor Defendant "made more than superficial efforts to pursue commercialization of Synacthen ... to protect Acthar monopoly pricing." (§ 172.) 14 months after Questcor purchased the rights to Synacthen, Defendant acquired Questcor for \$5.6 billion, an amount almost entirely attributable to the value of Acthar. (§ 171.) In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen in the United States. (§ 176.)

DEMURRER STANDARDS

"A demurrer tests the legal sufficiency of the factual allegations in a complaint." (*Redfearn v. Trader Joe's Co.* (2018) 20 Cal. App. 5th 989, 996.) "As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are deemed to be true, however improbable they may be," unless the "complaint contains allegations of fact inconsistent with attached documents, or allegations contrary to facts which are judicially noticed." (*Del E. Webb Corp. v. Structural Materials Co.* (1981) 123 Cal. App. 3d 593, 604.) Courts "construe the complaint 'liberally ... with a view to substantial justice between the parties[.]'" (*Goncharov v. Uber Techs., Inc.* (2018) 19 Cal. App. 5th 1157, 1165.)

"[I]f a plaintiff pleads a claim that fails to state a cause of action, a demurrer is properly sustained[.]" (*Boxer v. City of Beverly Hills* (2016) 246 Cal. App. 4th 1212, 1225.) "Where the complaint is defective, ... great liberality should be exercised in permitting a plaintiff to amend [the] complaint." (*Redfearn*, 20 Cal. App. 5th at 996.) "[L]ave to amend should not be granted where ... amendment would be futile." (*Id.* at 997.)

ANALYSIS OF DEMURRER

The Complaint alleges nine causes of action: (1) Violation of New Jersey RICO Statute (N.J.S.A. § 2C:41-2(c)); (2) Conspiracy to violate New Jersey RICO (N.J.S.A. § 2C:41-2(d)); (3) Monopolization under State Law, inter alia, Bus. & Prof. ("B&P") Code § 17200 et seq. and CA common law (and for violations of statute for 27 other states and territories); (4) Contract or Conspiracy in Restraint of Trade Under State Laws, inter alia, B&P Code §§ 17200 et seq., 16700 et seq., 16720 et seq., and 16750(a) (and the laws of 30 other states); (5) Unfair and Deceptive Practices under State Laws, inter alia, B&P Code § 17200 et seq. (and the laws of 33 other states); (6) fraud; (7) Insurance Fraud under State Law, inter alia, Cal. Ins. Code § 1871 et seq. (and the laws of 39 other states); (8) Tortious Interference with Contractual Relations; and (9) Unjust Enrichment.

The Court OVERRULES Defendant's Demurrer with respect to the Complaint's Counts 1, 2 (New Jersey RICO violations), 5 (Unfair and Deceptive Practices), 6 (Fraud), 7 (Insurance Fraud), and 9 (Unjust Enrichment). The Court SUSTAINS WITH LEAVE TO AMEND Defendant's Demurrer to the Complaint's Counts 3 (Monopolization), 4 (Contract or Conspiracy in Restraint of Trade) and 8 (Tortious Interference with Contractual Relations).

1. Demurrer to Complaint Counts 1 and 2 (New Jersey RICO Violations).

Plaintiff's First two Causes of Actions/Counts are brought under New Jersey's "Little RICO" statute at N.J.S.A. § 2C:41-2(c) and (d). N.J.S.A. § 2C:41-2(c) and (d) provide:

"c. It shall be unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

d. It shall be unlawful for any person to conspire as defined by N.J.S. 2C:5-2, to violate any of the provisions of this section."

§ 2C:5-2 is a statute which defines conspiracy under New Jersey law.

In interpreting New Jersey "Little RICO" statute, it is appropriate to seek guidance from federal decisions construing federal RICO provisions, since New Jersey statute borrows its structure, purpose and remedies from federal legislation. (*State v. Ball* (1993) 268 N.J.Super. 72, 98, affirmed at 141 N.J. 142; *Maxim Sewerage Corp. v. Monmouth Ridings* (1993) 273 N.J.Super. 84 (although New Jersey RICO statute is broader in application than federal RICO statute, New Jersey will still look to federal case law interpreting RICO to interpret same offense).)

To state a federal RICO claim, a plaintiff must allege "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." (*Odom v. Microsoft Corp.*, 486 F.3d 541, 547 (9th Cir. 2007) (quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985)). "[T]he conduct must be (5) the proximate cause of harm to the victim." (*Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 997 (9th Cir. 2014).) Racketeering activity "encompass dozens of state and federal offenses, known in RICO parlance as predicates." (*RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2096 (2016).) There is a pattern of racketeering activity where there is "a series of related predicates that together demonstrate the existence or threat of continued criminal activity." (*Id.* at 2096-97.) "[F]ailure to adequately plead a substantive violation of RICO precludes a claim for conspiracy." (*Howard v. Am. Online Inc.*, 208 F.3d 741, 751 (9th Cir. 2000).)

Plaintiff alleges the "Acthar Enterprise," consisting of Defendant, Express Scripts (and its subsidiaries), the Chronic Disease Fund ("CDF"), and the prescribing doctors, was "used as a tool to effectuate a pattern of racketeering activity." (Complaint ¶ 218.) Specifically, Defendant 1) made allegedly false statements, including that Defendant was in compliance with the laws, which constituted mail and wire fraud, as well as use of interstate facilities to conduct unlawful activity, and 2) subsidized co-pays through CDF and made payments to the prescribing doctors which "violated state commercial bribery statutes." (*Id.* ¶¶ 219-227, 149-159.)

In its Demurrer papers, Defendant does not directly attack the allegations of Counts 1 and 2 of Plaintiff's Complaint. Instead, Defendant contends that none of the underlying alleged unlawful conduct set forth in the Complaint -- namely (1) Defendant's "vertical integration" of distribution of Acthar, (2) Defendant's use of a charity to fund patient co-pays solely for use of Acthar, (3) Defendant's active, "improper or false" marketing of Acthar for off-label uses, (4) alleged "kickbacks" to doctors who regularly prescribe Acthar, and (5) purchasing the rights to Acthar's only potential competitor Synacthan in order to prevent Synacthen from entering the United States market -- state actionable conduct against Defendant. (See Moving MPA at pp. 17:20-21:28, 24:25-33:18.) Defendant also contends that Plaintiff's claims are time-barred by the applicable statutes of limitations. (*Id.* at pp. 22:1-24:4.)

The Court is not persuaded by either of Defendant's arguments. First, with respect to Defendant's argument that the applicable statutes of limitations have run because Plaintiff had notice of at least some of Defendant's alleged wrongful conduct going back to late 2013 (See Exhs. B-D to Defendant's Request for Judicial Notice in Support of Demurrer and Motion to Strike ("RJN")), the Complaint alleges at ¶¶ 177 and 180 that Defendant actively concealed the existence of its illegal scheme and the acts underlying it through false or misleading statements to Plaintiff and the public and that as a result of this "fraudulent concealment," HCSC could not have discovered and remained unaware of Defendant's wrongful conduct until the Federal Trade Commission and the U.S. Dept. of Justice brought this conduct to light through investigations, legal actions and/or settlements." Further, ¶ 181 alleges continuing injury to Plaintiff. The Court in considering a Demurrer must accept these allegations as true, no matter how unlikely, unless matters of which the Court may take judicial notice refute Plaintiff's allegations as a matter of law.

Although the late 2013 news articles published in *Barron's* and the *New York Times* are evidence tending to show that information regarding Defendant's allegedly improper relationship with CDF was readily available to Plaintiff, they do not as a matter of law establish that Plaintiff had constructive knowledge in 2013 or 2014 of the full extent of Defendant's "racketeering activities" alleged in the Complaint or even that Plaintiff had constructive knowledge of the alleged fraudulent relationship between Defendant and CDF. (See *Richtek USA, Inc. v. uPI Semiconductor Corp.* (2015) 242 Cal.App.4th 651, 660 ("When judicial notice is taken of a document, however, the truthfulness and proper interpretation of the document are disputable."))

Second, the Court finds that Plaintiff has sufficiently alleged a pattern of racketeering activity by Defendant. Plaintiff alleges that Defendant set up a distribution system, which through a subsidiary of Express Scripts, UBC, designed to facilitate and increase sales and prescriptions of Acthar by "interacting directly with patients and third-party payors by coordinating various patient assistance programs, including the ASAP and PAP programs described further below." (§ 80.) The Complaint alleges that Defendant set up through CDF co-pay charities the sole purpose of which was to eliminate or substantially reduce (see § 112) co-pays for Acthar to patients, so that patients and their doctors would have no incentive to request alternative, more cost-effective drugs, while leaving insurers like Plaintiff to pay their full portion of the allegedly exorbitant price of Acthar. (§§ 89-120.) The Complaint contains numerous, specific factual allegations regarding the degree to which Defendant intentionally and directly worked to connect patients with co-pay assistance funded by Defendant. (Ibid., see particularly §§ 106, 112 alleging that Defendant "implemented an "automatic offering" of co-pay assistance to all patients with co-pays greater than \$150, administered by UBC through [Defendant's] reimbursement hub [ASAP]. The ASAP program referred over 98% of the patients who received subsidies" from three Acthar funds operated by CDF.")

The Complaint further alleges that Defendants actively marketed off-label uses and unapproved dosing regimens to increase demand for Acthar, to make use of Acthar seem more price competitive and also to support misleading representations in marketing materials and by salespersons that Acthar was better tolerated than alternative medications, even though the off-label uses and unapproved dosing regimens were not supported by peer-reviewed studies showing Acthar to be as effective as less-costly alternatives. In fact, the Complaint alleges that Defendant's salespeople pre-filled insurance and prescription forms calling for an unvetted five-day dosing regimen referred to as the "Brod Protocol," so that doctors and other health care providers could more readily prescribe this unapproved dosing regimen. (§§ 121-146.)

The Complaint also alleges with respect to payments made by Defendants to doctors that in 2007, Defendant "knew that it might have priced itself out of the MS market;" Defendant "heavily marketed" Acthar to doctors who treated conditions such as MS, RA, and sarcoidosis; "Acthar had not been prescribed in large quantities for these conditions" prior to 2014; in 2014, Defendant's president told investors about "a strategy to expand Acthar's sales to patients" with these and other conditions even though "there were no new medical studies suggesting Acthar was needed to treat any of these conditions;" today, "fewer than 10% of Acthar's sales come from prescriptions for infantile spasms," the main use for which Acthar is a primary treatment; and 88% of doctors who submitted more than 10 claims for Acthar received payment from Defendant, while only 35% of all specialists "receive payments from the pharmaceutical industry." (§§ 89, 147-159.)

Finally, the Complaint alleges that Defendant "directly misrepresented to [Plaintiff] that it was complying with state and federal law, including laws related to bribery, kickbacks, and false claims" when Defendant submitted data for Prescription Drug Event (PDE) claims "certifying that such data is true, accurate, and complete." (§§ 34-39, 177-178, 200, 259, 267-270.) The Complaint also alleges that Defendant's misrepresentations were part of a fraudulent scheme to increase sales of Acthar and that Plaintiff was damaged thereby. (§§ 219, 224, 226-228.)

The Court finds that Counts 1 and 2 of the Complaint adequately state New Jersey RICO violation causes of action. Wherefore, the Court **OVERRULES** Defendant's Demurrer to Counts 1 and 2 of the Complaint.

2. Demurrer to Complaint Counts 5, 6, 7 and 9 for, respectively, State Law Unfair and Deceptive Practices, Fraud, State Law Insurance Fraud, and Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer to the Complaint's Fifth, Sixth, Seventh and Ninth Counts. Defendant's Demurrer MPA does not directly address each of these causes of action. Because the Court has found that Plaintiff has successfully alleged New Jersey "Little RICO" causes of action, the predicates for which involve unfair or deceptive business practices, fraud and insurance fraud, resulting in unjust enrichment to Defendant at Plaintiff's expense, the Court **OVERRULES** the Demurrer to these Counts.

3. Demurrer to Complaint Counts 3 and 4 for, respectively, Monopolization in Violation of State Laws and Contract or Conspiracy in Restraint of Trade in violation of State Law.

The Complaint's Third and Fourth Counts allege solely Defendant's purchase of the U.S. rights to the drug Synacthen from Novartis for the alleged monopolistic purpose of preventing Synacthen from ever competing with Acthar in the United States as the basis for these causes of action. Defendant contends in its MPA that the Complaint fails to allege the relevant Antitrust Market in which Acthar competes and also that the Complaint fails to allege that Plaintiff has been injured as a result of Defendant's alleged monopolistic actions. (See Moving MPA at pp. 30:1-33:18.)

The Court finds that Defendant's latter argument has more merit than the former. The Complaint alleges facts throughout that undercut Plaintiff's allegation that there is an "ACTH" market of which Acthar is the only current market participant for what Plaintiff has alleged are the off-label uses that now make up the majority of Acthar's sales. (Compare ¶¶ 182-199 with ¶¶ 6, 89, 147-148.) However, ¶¶ 185-186 of the Complaint can be read to identify a small ACTH Market with respect to treatment of infantile spasms and acute exacerbations of MS, for which Synacthen could be the only meaningful competitor to Acthar.

Defendant's argument that the Complaint fails to state facts establishing that Plaintiff has actually suffered damages has greater merit. Based on the facts alleged in the Complaint, Plaintiff is essentially alleging that for a period four years and one month between June 2013 (when Defendant purchased the U.S. rights to Synacthen from Novartis) until July 2017 (when Defendant, as part of a settlement with the FTC, sub-licensed the U.S. rights to Synacthen to West Therapeutic Development, LLC ("West") with the FTC's approval), Defendant wrongfully delayed development of Synacthen as an FDA-approved drug marketable in the U.S. (¶¶ 162-176.) Thus, Plaintiff's alleged damages for Defendant's alleged wrongful conduct can only be the difference between what Plaintiff paid for Acthar and what it would have paid for lower-cost Synacthen during the roughly 4.1 year period when Synacthen would have been on the U.S. market but for Defendant's monopolistic practices.

Moreover, based on the allegations of the Complaint, the only reasonable inference the Court can draw is that since July 2017, West has been working diligently and in good faith to secure FDA approval of Synacthen in the United States. There are also no facts alleged in the Complaint tending to show that, but for Defendant's wrongful conduct, Defendant could have secured FDA approval for Synacthen in a shorter period from its June 2013 purchase date than it will take West to secure FDA approval from West's July 2017 purchase date.

However, the Complaint filed on 2/27/2020 alleges neither that West has already secured FDA approval of Synacthen nor alleged any reasonable estimate regarding when the FDA will approve Synacthen or when Synacthen will actually be available for purchase in the U.S. As such, Plaintiff's claim for damages at present appears to be entirely speculative and hypothetical. For example, if it takes West ten years from purchase to bring Synacthen to the U.S. market, then a finder of fact could reasonably infer that it would have taken Defendant acting in good faith ten years from purchase to bring Synacthen to the U.S. market. If that were the case, Plaintiff would have no damages until the 4.1 year period between June 2023 and July 2027, when but for Defendant's alleged wrongful conduct Plaintiff would have been able to save money by purchasing Synacthen instead of Acthar.

"If the existence-and not the amount-of damages alleged in a fraud pleading is 'too remote, speculative or uncertain,' then the pleading cannot state a claim for relief." (Beckwith v. Dahl (2012) 205 Cal.App.4th 1039, 1064, citing Block v. Tobin (1975) 45 Cal.App.3d 214, 219.) As with fraud claims, "California requires a 'high degree of particularity' in the pleading" antitrust violations. (Freeman v. San Diego Ass'n of Realtors (1999) 77 Cal.App.4th 171, 196.)

In Opposition Plaintiff argues that the federal district court case *Tawfilis v. Allergan, Inc.* (C.D. Cal. 2015) 157 F.Supp.3d 853 supports a finding that Plaintiff has adequately alleged damages based solely on Defendant's alleged wrongful conduct regarding Synacthen. However, *Tawfilis* is distinguishable. While the underlying facts and claims of the dispute in *Tawfilis* are similar to the present action, the *Tawfilis* complaint contained much more detailed allegations than Plaintiff's Complaint does about the steps the potential competitor had taken so that its product *Innotox* could compete with defendant's *Botox* in the U.S. market, before the defendant purchased the U.S. rights to *Innotox* from its potential competitor. The additional alleged facts included the dates on which the competitor applied for and obtained U.S. patents, its plan to build a new manufacturing facility between the first quarter of 2012 and the first quarter of 2013 in order to increase production of *Innotox* for the entry into the U.S. market, and, most importantly, that *Innotox* "could have been approved for sale in the U.S. in less than two years following its obtaining regulatory approval abroad in mid-2013." (157 F.Supp.3d at 857.)

Based on these allegations, plaintiff Tawfilis could allege in his complaint actual damages at least by the time of trial, in light of the 10/20/2015 date on which the federal court's ruling on defendant's Motion to Dismiss entered. In contrast, Plaintiff's Complaint contains no allegations regarding what West has done to obtain FDA approval for Synacthen or when Synacthen might reasonably be available for purchase in the United States.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaints Third and Fourth Counts WITH LEAVE TO AMEND.

4. Demurrer to Complaint Count 8 for Tortious Interference with Contractual Relations.

The Complaint's Eighth Cause of Action appears to be an attempt to allege a cause of action for inducing breach of contract. (See CACI Jury Instruction No. 2200.) The elements of such a cause of action are: (1) the existence of a contract between plaintiff and a third party; (2) that defendant knew of the contract; (3) that defendant's conduct caused the third party to breach the contract; (4) plaintiff was harmed; and (5) defendant's conduct was a substantial factor in causing plaintiff's harm. (Ibid; Pacific Gas & Electric Co. v. Bear Stearns & Co. (1990) 50 Cal.3d 1118,1126.) The Court notes that CACI No. 2021 contains a separate jury instruction for "Intentional Inference with Contractual Relations" where plaintiff must show only that, inter alia, defendant's conduct "made performance [of the third party contract] more expensive or difficult." (PG&E, supra, 50 Cal.3d at 1129.)

As a cause of action for inducing breach of contract, the Eighth Cause of Action fails because this court agrees with the reasoning of the Court in Humana v. Mallinkrodt Ard LLC (C.D. Cal. 2020) 2020 WL 3041308 at p. *15, that patients' acceptances of co-pay assistance from a patient assistance program ("PAP"), even if the PAP does not comply with fraud and abuse laws, is not a breach of an insurance agreement that requires members to pay their share of costs for prescription drugs. (See RJN, Exh. A at p. 10.)

In Opposition, Plaintiff contends the 2005 Dept. Health and Human Services Office of Inspector General ("OIG") Bulletin published in the Federal Register relied upon by Defendant and the Humana Court only applies to Medicare Part D beneficiaries and does not apply to non-Medicare Part D beneficiaries who are some of Plaintiff's members. However, this Court considers the OIG guidance evidence of a public policy applicable to all health insurance contracts intended to enable patients with modest incomes to have access to medications, particularly where patients are unlikely to have any personal knowledge whether charity funds like those alleged to have been set up by Defendant do or do not follow legal requirements. Plaintiff specifically alleges that Defendant kept the fraudulent nature of its charities a secret for years. (§§ 177-180.) Where Plaintiff expressly alleges that it, a large and sophisticated player in the health care and medications markets "with more than 16 million members" (§ 17), could not figure out what Defendant was allegedly up to until federal agencies became involved (§ 180), this Court will not impose greater knowledge requirements or duties to investigate on patients.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaint's Count 8 WITH LEAVE TO AMEND. In an amended pleading, Plaintiff may seek to state a cause of action under either of CACI Nos. 2200 or 2201.

MOTION TO STRIKE

MOTION TO STRIKE STANDARDS

"The court may, upon a motion . . . or at any time in its discretion, and upon terms it deems proper: (a) [s]trike out any irrelevant, false, or improper matter inserted in any pleading[;] . . . [and/or] (b) [s]trike out all or any part of any pleading not drawn or filed in conformity with the laws of this state, a court rule, or an order of the court." (CCP § 436.) An "irrelevant matter," or "immaterial allegation," means: (1) an allegation that is not essential to the statement of a claim or defense; (2) an allegation that is neither pertinent to nor supported by an otherwise sufficient claim or defense; or (3) a demand for judgment requesting relief not supported by the allegations of the complaint or cross-complaint. (CCP § 431.10(b).)

ANALYSIS OF DEFENDANT'S MOTION TO STRIKE

The Court DENIES Defendant's Motion to Strike §§ 76-85 regarding Defendant's "vertical integration"

of distribution of Acthar. The Court is not persuaded by Plaintiff's arguments that Defendant's actions to limit distribution to a single distributor, Express Scripts, artificially maintained the price of Acthar because it prevented multiple distributors from negotiating to lower prices, because Defendant was still the only producer of Acthar and could thereby set whatever price it wished regardless of the number of distributors in dealt with. Nevertheless, these paragraphs are relevant to the Complaint as a whole because, for example, they allege that the "integrated services [were] critical to the scheme" (§ 78) because they enabled Defendant to funnel patients using Acthar into Defendant's fraudulent ASAP and PAPs. (§§ 80-84.) Further, § 85 contains allegations relevant to Plaintiff's damages claims.

The Court DENIES Defendant's Motion to Strike §§ 89-120. The Court has found that these paragraphs allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 223 at p. 43:5-6. Defendant does not properly identify the portion § 223 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, while the Court agrees with Defendant and the Humana Court at p. * 13 that co-pay assistance paid by a PAP to patient does not constitute a commercial bribe, the Complaint also alleges Defendant paid "bribes" and "kickbacks" to doctors to prescribe Acthar. N.J.S.A. § 2C:21-10 specifically references a "physician" as a person with a "duty of fidelity" to whom a bribe might be given as consideration for knowing violation of said duty of fidelity.

The Court DENIES Defendant's Motion to Strike §§ 273-275. The Court has found above that the allegations underlying the allegations in these paragraphs are sufficient to allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 281 at p. 56:22. Defendant does not properly identify the portion § 281 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, The Court has found above that the allegations underlying the relevant allegation in these paragraph are sufficient to allege actionable conduct against Defendant.

The Court DENIES Defendant's Motion to Strike §§ 14, 149-161, 259, 272-273. The Court has found above that these allegations are sufficient to state actionable conduct against defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike "§ 181, Ins. 21-22." The Complaint contains no matter meeting this description. (See also CRC Rule 3.1322(a).)

The Court DENIES Defendant's Motion to Strike §§ 13, 121-148. The allegations are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike §§ 15, 162-176, 244-247, 249-253. Plaintiff's allegations regarding Defendant's alleged efforts to prevent competitor drug Synacthen from the U.S. market are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike § 200. Defendant's Notice appears to seek to strike only a portion of § 200, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike § 203. Defendant's Notice appears to seek to strike only a portion of § 203, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike §§ 161 and 175. While Defendant's settlement of legal claims brought by the U.S. Justice Dept. and the FTC are not admissible as evidence of wrongful conduct, the allegations could be relevant as evidence regarding when Plaintiff allegedly learned or was put on notice of Defendant's wrongful conduct.

The Court DENIES Defendant's Motion to Strike §§ 245, 253, 257 and 280. This trial Court does not have the resources to examine each of the 133 referenced statutes from approximately 40 different jurisdictions, which "the Court determines to be subject to a legal bar." The Court notes that it authorized, and Defendant filed, a 25-page moving MPA and a 15-page Reply Brief. The Court will not address issues not properly raised in the substantial briefing.

With respect to Defendants' Request for Judicial Notice ("RJN") Exhs. A-I, the Court GRANTS

judicial notice of the existence of the documents but does not take judicial notice of the truth of the matters stated therein. (See *Licudine v. Cedars-Sinai Med. Ctr.* (2016) 3 Cal.App.5th 881, 902, quoting *In re Joseph H.* (2015) 237 Cal.App.4th 517, 541-542 ("[w]e can take judicial notice of official acts and public records, but we cannot take judicial notice of the truth of the matters stated therein.") The Court GRANTS Defendants' RJN with respect to Exh. J. The Court GRANTS Defendants' RJN with respect to Exhs. K-O only with respect to the non-California legal authorities stated therein; the Court does not take judicial notice of the statements that appear to be legal argument regarding the interpretation of those non-California legal authorities.

The Court GRANTS Plaintiff's RJN with respect to Exh. 1 to the Opp. Weiler Dec. The Court GRANTS Plaintiff's RJN with respect to the existence of Exhs. 2 and 3 to the Opp. Weiler Dec. but does not take judicial notice of the truth of the facts asserted therein.

Dated: 08/19/2020

 Facsimile

Judge Stephen Kaus

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Case Number: RG20056354
Order After Hearing Re: of 08/19/2020

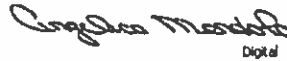
DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 08/21/2020.

Chad Finke Executive Officer / Clerk of the Superior Court

By


Digital

Deputy Clerk

EXHIBIT 59

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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Order

Motion to Strike

The Motion to Strike was set for hearing on 08/19/2020 at 03:00 PM in Department 19 before the Honorable Stephen Kaus. The Tentative Ruling was published and was contested.

IT IS HEREBY ORDERED THAT:

With respect to defendants Mallinckrodt Ard LLC's and Mallinckrodt plc's (collectively "Defendant") Demurrer to and Motion to Strike Portions of plaintiff Health Care Service Corp.'s ("Plaintiff") Complaint, the Court **ORDERS THE PARTIES TO APPEAR** for hearing, which will be conducted on Tuesday, August 25, 2020 at 9:00 a.m. in Dept. 19. The hearing will be conducted using the Bluejeans Teleconference Network. Dept. 19 will send invitations to the parties to participate in the hearing via Bluejeans in advance of the 8/25/2020 hearing date.

In order to facilitate the discussion at the 8/25/2020 hearing, the Court provides the following substantive Tentative Ruling on the Demurrer and Motion to Strike.

The Court **SUSTAINS IN PART** and **OVERRULES IN PART** Defendant's Demurrer as set forth below. The Court **DENIES** Defendant's Motion to Strike in its entirety as set forth below.

Plaintiff's Complaint alleges nine Causes of Action based on allegations that it was damaged by Defendants' monopolistic and illegal practices with respect to an adrenocorticotrophic hormone ("ACTH") analogue drug called Acthar, which is used, inter alia, as an anti-inflammatory drug.

FACTS

The Complaint alleges the following relevant facts. Defendant produces H.P. Acthar Gel (Acthar), a drug that was invented in 1948 and first approved by the FDA in 1952. (Complaint ¶¶ 2, 5, 57.) Acthar was approved to treat multiple sclerosis ("MS") in 1979 and to treat infantile spasms in 2010. (Id. ¶¶ 60, 67.) The latter condition is the only one for which Acthar may be considered the most effective "first line" treatment. (Id. at ¶ 67.) Acthar has also been approved for use of idiopathic membranous nephropathy, exacerbations of dermatomyositis (polymyositis), sarcoidosis, and inflammatory eye disease, and as an adjunct therapy to improve effectiveness of primary therapies for psoriatic and rheumatoid arthritis ("RA"). (¶ 64.) As of the filing of the Complaint, Acthar represents 100% of the market for ACTH drugs in the United States. (¶ 183.)

Plaintiff is the nation's largest customer-owned insurer, is an independent licensee of Blue Cross and

Order

Blue Shield Association ("BCBSA"), and has an exclusive license to offer BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma and Texas. Plaintiff through its operating divisions and subsidiaries provides Medicare benefits through contracts with the Centers for Medicare and Medicaid Services, provides benefits under various states' Medicaid programs; and private commercial health insurance benefits. Many of the plans operated by Plaintiff offer prescription drug coverage under which claims for Acthar were submitted and paid by Plaintiff. Plaintiff seeks to recover pursuant to those paid claims. (Id., ¶¶ 17-19.)

Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. (Id. ¶¶ 5, 56.) As a result of the later development of synthetic steroid drugs and non-steroidal anti-inflammatory drugs, by the 1990's only a few key uses, such as for treating infantile spasms, remained for Acthar; and the drug became unprofitable at its then price for then manufacturer Aventis Pharmaceuticals. (¶¶ 6-7.) In 2001, Aventis sold Acthar's rights to Defendant's predecessor Questcor for \$100,000. Questcor raised the price of Acthar from \$40 per unit to \$750 per unit immediately after purchase, to \$1,650 per unit by 2007, at which time the price was raised to \$23,269 per unit. As of 2018, the price had further increased to \$38,892 per unit, such that a single three-unit course of treatment costs nearly \$120,000. (¶¶ 7-8.) Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from just under \$50 million in 2011 to \$636 million in 2016. (¶¶ 72-73.)

Plaintiff alleges that it has paid more than \$100 million for Acthar "during the relevant period," later apparently defined as from 2011 through the present. (¶¶ 85, 200.) Defendant merged with Questcor in August 2014. (¶ 9.)

In June 2007, Defendant "vertically integrated" its sales by distributing Acthar exclusively through the specialty pharmacy CuraScript, a subsidiary of Express Scripts. CuraScript "is paid a fixed fee for each vial of Acthar" and has the right to return to Defendant any inventory "which goes unsold before its expiration date. (¶¶ 76-84.)

The Complaint alleges that starting in 2010, Defendant established a number of non-profit funds designed to provide assistance to consumers prescribed Acthar to make co-payments required under their health care plans. Defendant set up funds to pay for medications used to treat MS, lupis and RA, which illegally reimbursed co-pays solely for prescriptions of Acthar through 2014. (¶¶ 89-119.) The Complaint alleges on information and belief that Defendant continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 through the present. (¶ 120.)

The Complaint alleges that Defendant began to actively promote off-label uses of Acthar in order to increase sales of the drug. Questcor marketed the drug to focus on "patient types" including those who had had adverse reactions or tolerability problems with IV steroids, even though "common adverse reactions for [Acthar] are similar to those of corticosteroids," which are much less expensive. (¶¶ 121-129.) Questcor's written marketing materials created a false impression that Acthar was better tolerated than steroids. (¶¶ 131-133.) Further, Questcor promoted the so-called "Brod Protocol" requiring a shorter five-day, one vial regimen for Acthar even though there were no peer-reviewed studies showing that Acthar was as effective as less costly alternative drug regimens. Even though this was an admitted off-schedule use of Acthar, Questcor sales representatives routinely told doctors that they should prescribe the five-day regimen and prepared prescription forms with the five-day dosing regimen already written in. (¶¶ 134-145.)

The Complaint further alleges that Defendant paid "kick-backs" to doctors who prescribed Acthar. Defendant did so through a paid speaker program, whereby doctor participants could receive \$2,000 per presentation and up to \$6,000 a day. This was at the high end of industry standard, but a speaking engagement could be to as few as three people who need not be physicians. Approximately, 90% of all Acthar prescriptions are written by approved speakers. Between 2013 and 2016, Defendant paid doctors nearly \$27.5 million in Acthar related payments. (¶¶ 149-156.) A 2018 study published in JAMA Network Open, which appears to use 2015 data, concludes that "aggressive sales tactics and payments from [Defendant] may influence prescribing behavior for [Acthar]." (¶ 158.) Nine doctors who prescribed between \$567,000 and \$3.05 million in Acthar received payments between \$44,000 and \$480,000, although the amounts prescribed by and the amounts paid to each such doctor are not directly proportional. (¶ 159.)

Synacthen is a synthetic ACTH drug approved for sale outside of the United States, where it is used for

the same purposes as Acthar. (§ 162.) In late 2011, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Three other companies engaged in several rounds of negotiations with Novartis with the intent to develop and use Synacthen to compete with Acthar at a lower price. (§§ 164-166.) Questcor had "inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer." Yet, Questcor's June 2013 bid, at a minimum of \$135 million, was several multiples higher than the other three bidders, who all submitted comparable offers in terms of value and structure. (§§ 168-169.) However, neither Questcor nor Defendant "made more than superficial efforts to pursue commercialization of Synacthen ... to protect Acthar monopoly pricing." (§ 172.) 14 months after Questcor purchased the rights to Synacthen, Defendant acquired Questcor for \$5.6 billion, an amount almost entirely attributable to the value of Acthar. (§ 171.) In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen in the United States. (§ 176.)

DEMURRER STANDARDS

"A demurrer tests the legal sufficiency of the factual allegations in a complaint." (Redfearn v. Trader Joe's Co. (2018) 20 Cal. App. 5th 989, 996.) "As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are deemed to be true, however improbable they may be," unless the "complaint contains allegations of fact inconsistent with attached documents, or allegations contrary to facts which are judicially noticed." (Del E. Webb Corp. v. Structural Materials Co. (1981) 123 Cal. App. 3d 593, 604.) Courts "construe the complaint 'liberally ... with a view to substantial justice between the parties[.]'" (Goncharov v. Uber Techs., Inc. (2018) 19 Cal. App. 5th 1157, 1165.)

"[I]f a plaintiff pleads a claim that fails to state a cause of action, a demurrer is properly sustained[.]" (Boxer v. City of Beverly Hills (2016) 246 Cal. App. 4th 1212, 1225.) "Where the complaint is defective, ... great liberality should be exercised in permitting a plaintiff to amend [the] complaint." (Redfearn, 20 Cal. App. 5th at 996.) "[L]ave to amend should not be granted where ... amendment would be futile." (Id. at 997.)

ANALYSIS OF DEMURRER

The Complaint alleges nine causes of action: (1) Violation of New Jersey RICO Statute (N.J.S.A. § 2C:41-2(c)); (2) Conspiracy to violate New Jersey RICO (N.J.S.A. § 2C:41-2(d)); (3) Monopolization under State Law, inter alia, Bus. & Prof. ("B&P") Code § 17200 et seq. and CA common law (and for violations of statute for 27 other states and territories); (4) Contract or Conspiracy in Restraint of Trade Under State Laws, inter alia, B&P Code §§ 17200 et seq., 16700 et seq., 16720 et seq., and 16750(a) (and the laws of 30 other states); (5) Unfair and Deceptive Practices under State Laws, inter alia, B&P Code § 17200 et seq. (and the laws of 33 other states); (6) fraud; (7) Insurance Fraud under State Law, inter alia, Cal. Ins. Code § 1871 et seq. (and the laws of 39 other states); (8) Tortious Interference with Contractual Relations; and (9) Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer with respect to the Complaint's Counts 1, 2 (New Jersey RICO violations), 5 (Unfair and Deceptive Practices), 6 (Fraud), 7 (Insurance Fraud), and 9 (Unjust Enrichment). The Court **SUSTAINS WITH LEAVE TO AMEND** Defendant's Demurrer to the Complaint's Counts 3 (Monopolization), 4 (Contract or Conspiracy in Restraint of Trade) and 8 (Tortious Interference with Contractual Relations).

1. Demurrer to Complaint Counts 1 and 2 (New Jersey RICO Violations).

Plaintiff's First two Causes of Actions/Counts are brought under New Jersey's "Little RICO" statute at N.J.S.A. § 2C:41-2(c) and (d). N.J.S.A. § 2C:41-2(c) and (d) provide:

"c. It shall be unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

d. It shall be unlawful for any person to conspire as defined by N.J.S. 2C:5-2, to violate any of the provisions of this section."

§ 2C:5-2 is a statute which defines conspiracy under New Jersey law.

In interpreting New Jersey "Little RICO" statute, it is appropriate to seek guidance from federal decisions construing federal RICO provisions, since New Jersey statute borrows its structure, purpose and remedies from federal legislation. (State v. Ball (1993) 268 N.J.Super. 72, 98, affirmed at 141 N.J. 142; Maxim Sewerage Corp. v. Monmouth Ridings (1993) 273 N.J.Super. 84 (although New Jersey RICO statute is broader in application than federal RICO statute, New Jersey will still look to federal case law interpreting RICO to interpret same offense).)

To state a federal RICO claim, a plaintiff must allege "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." (Odom v. Microsoft Corp., 486 F.3d 541, 547 (9th Cir. 2007) (quoting Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985)). "[T]he conduct must be (5) the proximate cause of harm to the victim." (Eclectic Properties E., LLC v. Marcus & Millichap Co., 751 F.3d 990, 997 (9th Cir. 2014).) Racketeering activity "encompass dozens of state and federal offenses, known in RICO parlance as predicates." (RJR Nabisco, Inc. v. European Cmty., 136 S. Ct. 2090, 2096 (2016).) There is a pattern of racketeering activity where there is "a series of related predicates that together demonstrate the existence or threat of continued criminal activity." (Id. at 2096-97.) "[F]ailure to adequately plead a substantive violation of RICO precludes a claim for conspiracy." (Howard v. Am. Online Inc., 208 F.3d 741, 751 (9th Cir. 2000).)

Plaintiff alleges the "Acthar Enterprise," consisting of Defendant, Express Scripts (and its subsidiaries), the Chronic Disease Fund ("CDF"), and the prescribing doctors, was "used as a tool to effectuate a pattern of racketeering activity." (Complaint ¶ 218.) Specifically, Defendant 1) made allegedly false statements, including that Defendant was in compliance with the laws, which constituted mail and wire fraud, as well as use of interstate facilities to conduct unlawful activity, and 2) subsidized co-pays through CDF and made payments to the prescribing doctors which "violated state commercial bribery statutes." (Id. ¶¶ 219-227, 149-159.)

In its Demurrer papers, Defendant does not directly attack the allegations of Counts 1 and 2 of Plaintiff's Complaint. Instead, Defendant contends that none the underlying alleged unlawful conduct set forth in the Complaint -- namely (1) Defendant's "vertical integration" of distribution of Acthar, (2) Defendant's use of a charity to fund patient co-pays solely for use of Acthar, (3) Defendant's active, "improper or false" marketing of Acthar for off-label uses, (4) alleged "kickbacks" to doctors who regularly prescribe Acthar, and (5) purchasing the rights to Acthar's only potential competitor Synacthan in order to prevent Synacthan from entering the United States market -- state actionable conduct against Defendant. (See Moving MPA at pp. 17:20-21:28, 24:25-33:18.) Defendant also contends that Plaintiff's claims are time-barred by the applicable statutes of limitations. (Id. at pp. 22:1-24:4.)

The Court is not persuaded by either of Defendant's arguments. First, with respect to Defendant's argument that the applicable statutes of limitations have run because Plaintiff had notice of at least some of Defendant's alleged wrongful conduct going back to late 2013 (See Exhs. B-D to Defendant's Request for Judicial Notice in Support of Demurrer and Motion to Strike ("RJN")), the Complaint alleges at ¶¶ 177 and 180 that Defendant actively concealed the existence of its illegal scheme and the acts underlying it through false or misleading statements to Plaintiff and the public and that as a result of this "fraudulent concealment," HCSC could not have discovered and remained unaware of Defendant's wrongful conduct until the Federal Trade Commission and the U.S. Dept. of Justice brought this conduct to light through investigations, legal actions and/or settlements." Further, ¶ 181 alleges continuing injury to Plaintiff. The Court in considering a Demurrer must accept these allegations as true, no matter how unlikely, unless matters of which the Court may take judicial notice refute Plaintiff's allegations as a matter of law.

Although the late 2013 news articles published in Barron's and the New York Times are evidence tending to show that information regarding Defendant's allegedly improper relationship with CDF was readily available to Plaintiff, they do not as a matter of law establish that Plaintiff had constructive knowledge in 2013 or 2014 of the full extent of Defendant's "racketeering activities" alleged in the Complaint or even that Plaintiff had constructive knowledge of the alleged fraudulent relationship between Defendant and CDF. (See Richtek USA, Inc. v. uPI Semiconductor Corp. (2015) 242 Cal.App.4th 651, 660 ("When judicial notice is taken of a document, however, the truthfulness and proper interpretation of the document are disputable."))

Second, the Court finds that Plaintiff has sufficiently alleged a pattern of racketeering activity by Defendant. Plaintiff alleges that Defendant set up a distribution system, which through a subsidiary of Express Scripts, UBC, designed to facilitate and increase sales and prescriptions of Acthar by "interacting directly with patients and third-party payors by coordinating various patient assistance programs, including the ASAP and PAP programs described further below." (§ 80.) The Complaint alleges that Defendant set up through CDF co-pay charities the sole purpose of which was to eliminate or substantially reduce (see § 112) co-pays for Acthar to patients, so that patients and their doctors would have no incentive to request alternative, more cost-effective drugs, while leaving insurers like Plaintiff to pay their full portion of the allegedly exorbitant price of Acthar. (§§ 89-120.) The Complaint contains numerous, specific factual allegations regarding the degree to which Defendant intentionally and directly worked to connect patients with co-pay assistance funded by Defendant. (Ibid., see particularly §§ 106, 112 alleging that Defendant "implemented an "automatic offering" of co-pay assistance to all patients with co-pays greater than \$150, administered by UBC through [Defendant's] reimbursement hub [ASAP]. The ASAP program referred over 98% of the patients who received subsidies" from three Acthar funds operated by CDF.")

The Complaint further alleges that Defendants actively marketed off-label uses and unapproved dosing regimens to increase demand for Acthar, to make use of Acthar seem more price competitive and also to support misleading representations in marketing materials and by salespersons that Acthar was better tolerated than alternative medications, even though the off-label uses and unapproved dosing regimens were not supported by peer-reviewed studies showing Acthar to be as effective as less-costly alternatives. In fact, the Complaint alleges that Defendant's salespeople pre-filled insurance and prescription forms calling for an unvetted five-day dosing regimen referred to as the "Brod Protocol," so that doctors and other health care providers could more readily prescribe this unapproved dosing regimen. (§§ 121-146.)

The Complaint also alleges with respect to payments made by Defendants to doctors that in 2007, Defendant "knew that it might have priced itself out of the MS market;" Defendant "heavily marketed" Acthar to doctors who treated conditions such as MS, RA, and sarcoidosis; "Acthar had not been prescribed in large quantities for these conditions" prior to 2014; in 2014, Defendant's president told investors about "a strategy to expand Acthar's sales to patients" with these and other conditions even though "there were no new medical studies suggesting Acthar was needed to treat any of these conditions;" today, "fewer than 10% of Acthar's sales come from prescriptions for infantile spasms," the main use for which Acthar is a primary treatment; and 88% of doctors who submitted more than 10 claims for Acthar received payment from Defendant, while only 35% of all specialists "receive payments from the pharmaceutical industry." (§§ 89, 147-159.)

Finally, the Complaint alleges that Defendant "directly misrepresented to [Plaintiff] that it was complying with state and federal law, including laws related to bribery, kickbacks, and false claims" when Defendant submitted data for Prescription Drug Event (PDE) claims "certifying that such data is true, accurate, and complete." (§§ 34-39, 177-178, 200, 259, 267-270.) The Complaint also alleges that Defendant's misrepresentations were part of a fraudulent scheme to increase sales of Acthar and that Plaintiff was damaged thereby. (§§ 219, 224, 226-228.)

The Court finds that Counts 1 and 2 of the Complaint adequately state New Jersey RICO violation causes of action. Wherefore, the Court **OVERRULES** Defendant's Demurrer to Counts 1 and 2 of the Complaint.

2. Demurrer to Complaint Counts 5, 6, 7 and 9 for, respectively, State Law Unfair and Deceptive Practices, Fraud, State Law Insurance Fraud, and Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer to the Complaint's Fifth, Sixth, Seventh and Ninth Counts. Defendant's Demurrer MPA does not directly address each of these causes of action. Because the Court has found that Plaintiff has successfully alleged New Jersey "Little RICO" causes of action, the predicates for which involve unfair or deceptive business practices, fraud and insurance fraud, resulting in unjust enrichment to Defendant at Plaintiff's expense, the Court **OVERRULES** the Demurrer to these Counts.

3. Demurrer to Complaint Counts 3 and 4 for, respectively, Monopolization in Violation of State Laws and Contract or Conspiracy in Restraint of Trade in violation of State Law.

The Complaint's Third and Fourth Counts allege solely Defendant's purchase of the U.S. rights to the drug Synacthen from Novartis for the alleged monopolistic purpose of preventing Synacthen from ever competing with Acthar in the United States as the basis for these causes of action. Defendant contends in its MPA that the Complaint fails to allege the relevant Antitrust Market in which Acthar competes and also that the Complaint fails to allege that Plaintiff has been injured as a result of Defendant's alleged monopolistic actions. (See Moving MPA at pp. 30:1-33:18.)

The Court finds that Defendant's latter argument has more merit than the former. The Complaint alleges facts throughout that undercut Plaintiff's allegation that there is an "ACTH" market of which Acthar is the only current market participant for what Plaintiff has alleged are the off-label uses that now make up the majority of Acthar's sales. (Compare ¶¶ 182-199 with ¶¶ 6, 89, 147-148.) However, ¶¶ 185-186 of the Complaint can be read to identify a small ACTH Market with respect to treatment of infantile spasms and acute exacerbations of MS, for which Synacthen could be the only meaningful competitor to Acthar.

Defendant's argument that the Complaint fails to state facts establishing that Plaintiff has actually suffered damages has greater merit. Based on the facts alleged in the Complaint, Plaintiff is essentially alleging that for a period four years and one month between June 2013 (when Defendant purchased the U.S. rights to Synacthen from Novartis) until July 2017 (when Defendant, as part of a settlement with the FTC, sub-licensed the U.S. rights to Synacthen to West Therapeutic Development, LLC ("West") with the FTC's approval), Defendant wrongfully delayed development of Synacthen as an FDA-approved drug marketable in the U.S. (¶¶ 162-176.) Thus, Plaintiff's alleged damages for Defendant's alleged wrongful conduct can only be the difference between what Plaintiff paid for Acthar and what it would have paid for lower-cost Synacthen during the roughly 4.1 year period when Synacthen would have been on the U.S. market but for Defendant's monopolistic practices.

Moreover, based on the allegations of the Complaint, the only reasonable inference the Court can draw is that since July 2017, West has been working diligently and in good faith to secure FDA approval of Synacthen in the United States. There are also no facts alleged in the Complaint tending to show that, but for Defendant's wrongful conduct, Defendant could have secured FDA approval for Synacthen in a shorter period from its June 2013 purchase date than it will take West to secure FDA approval from West's July 2017 purchase date.

However, the Complaint filed on 2/27/2020 alleges neither that West has already secured FDA approval of Synacthen nor alleged any reasonable estimate regarding when the FDA will approve Synacthen or when Synacthen will actually be available for purchase in the U.S. As such, Plaintiff's claim for damages at present appears to be entirely speculative and hypothetical. For example, if it takes West ten years from purchase to bring Synacthen to the U.S. market, then a finder of fact could reasonably infer that it would have taken Defendant acting in good faith ten years from purchase to bring Synacthen to the U.S. market. If that were the case, Plaintiff would have no damages until the 4.1 year period between June 2023 and July 2027, when but for Defendant's alleged wrongful conduct Plaintiff would have been able to save money by purchasing Synacthen instead of Acthar.

"If the existence-and not the amount-of damages alleged in a fraud pleading is 'too remote, speculative or uncertain,' then the pleading cannot state a claim for relief." (Beckwith v. Dahl (2012) 205 Cal.App.4th 1039, 1064, citing Block v. Tobin (1975) 45 Cal.App.3d 214, 219.) As with fraud claims, "California requires a 'high degree of particularity' in the pleading" antitrust violations. (Freeman v. San Diego Ass'n of Realtors (1999) 77 Cal.App.4th 171, 196.)

In Opposition Plaintiff argues that the federal district court case *Tawfilis v. Allergan, Inc.* (C.D. Cal. 2015) 157 F.Supp.3d 853 supports a finding that Plaintiff has adequately alleged damages based solely on Defendant's alleged wrongful conduct regarding Synacthen. However, *Tawfilis* is distinguishable. While the underlying facts and claims of the dispute in *Tawfilis* are similar to the present action, the *Tawfilis* complaint contained much more detailed allegations than Plaintiff's Complaint does about the steps the potential competitor had taken so that its product Innotox could compete with defendant's Botox in the U.S. market, before the defendant purchased the U.S. rights to Innotox from its potential competitor. The additional alleged facts included the dates on which the competitor applied for and obtained U.S. patents, its plan to build a new manufacturing facility between the first quarter of 2012 and the first quarter of 2013 in order to increase production of Innotox for the entry into the U.S. market, and, most importantly, that Innotox "could have been approved for sale in the U.S. in less than two years following its obtaining regulatory approval abroad in mid-2013." (157 F.Supp.3d at 857.)

Based on these allegations, plaintiff Tawfilis could allege in his complaint actual damages at least by the time of trial, in light of the 10/20/2015 date on which the federal court's ruling on defendant's Motion to Dismiss entered. In contrast, Plaintiff's Complaint contains no allegations regarding what West has done to obtain FDA approval for Synacthen or when Synacthen might reasonably be available for purchase in the United States.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaints Third and Fourth Counts WITH LEAVE TO AMEND.

4. Demurrer to Complaint Count 8 for Tortious Interference with Contractual Relations.

The Complaint's Eighth Cause of Action appears to be an attempt to allege a cause of action for inducing breach of contract. (See CACI Jury Instruction No. 2200.) The elements of such a cause of action are: (1) the existence of a contract between plaintiff and a third party; (2) that defendant knew of the contract; (3) that defendant's conduct caused the third party to breach the contract; (4) plaintiff was harmed; and (5) defendant's conduct was a substantial factor in causing plaintiff's harm. (Ibid; Pacific Gas & Electric Co. v. Bear Stearns & Co. (1990) 50 Cal.3d 1118,1126.) The Court notes that CACI No. 2021 contains a separate jury instruction for "Intentional Inference with Contractual Relations" where plaintiff must show only that, inter alia, defendant's conduct "made performance [of the third party contract] more expensive or difficult." (PG&E, supra, 50 Cal.3d at 1129.)

As a cause of action for inducing breach of contract, the Eighth Cause of Action fails because this court agrees with the reasoning of the Court in Humana v. Mallinkrodt Ard LLC (C.D. Cal. 2020) 2020 WL 3041308 at p. *15, that patients' acceptances of co-pay assistance from a patient assistance program ("PAP"), even if the PAP does not comply with fraud and abuse laws, is not a breach of an insurance agreement that requires members to pay their share of costs for prescription drugs. (See RJN, Exh. A at p. 10.)

In Opposition, Plaintiff contends the 2005 Dept. Health and Human Services Office of Inspector General ("OIG") Bulletin published in the Federal Register relied upon by Defendant and the Humana Court only applies to Medicare Part D beneficiaries and does not apply to non-Medicare Part D beneficiaries who are some of Plaintiff's members. However, this Court considers the OIG guidance evidence of a public policy applicable to all health insurance contracts intended to enable patients with modest incomes to have access to medications, particularly where patients are unlikely to have any personal knowledge whether charity funds like those alleged to have been set up by Defendant do or do not follow legal requirements. Plaintiff specifically alleges that Defendant kept the fraudulent nature of its charities a secret for years. (§§ 177-180.) Where Plaintiff expressly alleges that it, a large and sophisticated player in the health care and medications markets "with more than 16 million members" (§ 17), could not figure out what Defendant was allegedly up to until federal agencies became involved (§ 180), this Court will not impose greater knowledge requirements or duties to investigate on patients.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaint's Count 8 WITH LEAVE TO AMEND. In an amended pleading, Plaintiff may seek to state a cause of action under either of CACI Nos. 2200 or 2201.

MOTION TO STRIKE

MOTION TO STRIKE STANDARDS

"The court may, upon a motion . . . or at any time in its discretion, and upon terms it deems proper: (a) [s]trike out any irrelevant, false, or improper matter inserted in any pleading[;] . . . [and/or] (b) [s]trike out all or any part of any pleading not drawn or filed in conformity with the laws of this state, a court rule, or an order of the court." (CCP § 436.) An "irrelevant matter," or "immaterial allegation," means: (1) an allegation that is not essential to the statement of a claim or defense; (2) an allegation that is neither pertinent to nor supported by an otherwise sufficient claim or defense; or (3) a demand for judgment requesting relief not supported by the allegations of the complaint or cross-complaint. (CCP § 431.10(b).)

ANALYSIS OF DEFENDANT'S MOTION TO STRIKE

The Court DENIES Defendant's Motion to Strike §§ 76-85 regarding Defendant's "vertical integration"

of distribution of Acthar. The Court is not persuaded by Plaintiff's arguments that Defendant's actions to limit distribution to a single distributor, Express Scripts, artificially maintained the price of Acthar because it prevented multiple distributors from negotiating to lower prices, because Defendant was still the only producer of Acthar and could thereby set whatever price it wished regardless of the number of distributors in dealt with. Nevertheless, these paragraphs are relevant to the Complaint as a whole because, for example, they allege that the "integrated services [were] critical to the scheme" (§ 78) because they enabled Defendant to funnel patients using Acthar into Defendant's fraudulent ASAP and PAPs. (§§ 80-84.) Further, § 85 contains allegations relevant to Plaintiff's damages claims.

The Court DENIES Defendant's Motion to Strike §§ 89-120. The Court has found that these paragraphs allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 223 at p. 43:5-6. Defendant does not properly identify the portion § 223 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, while the Court agrees with Defendant and the Humana Court at p. * 13 that co-pay assistance paid by a PAP to patient does not constitute a commercial bribe, the Complaint also alleges Defendant paid "bribes" and "kickbacks" to doctors to prescribe Acthar. N.J.S.A. § 2C:21-10 specifically references a "physician" as a person with a "duty of fidelity" to whom a bribe might be given as consideration for knowing violation of said duty of fidelity.

The Court DENIES Defendant's Motion to Strike §§ 273-275. The Court has found above that the allegations underlying the allegations in these paragraphs are sufficient to allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 281 at p. 56:22. Defendant does not properly identify the portion § 281 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, The Court has found above that the allegations underlying the relevant allegation in these paragraph are sufficient to allege actionable conduct against Defendant.

The Court DENIES Defendant's Motion to Strike §§ 14, 149-161, 259, 272-273. The Court has found above that these allegations are sufficient to state actionable conduct against defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike "§ 181, Ins. 21-22." The Complaint contains no matter meeting this description. (See also CRC Rule 3.1322(a).)

The Court DENIES Defendant's Motion to Strike §§ 13, 121-148. The allegations are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike §§ 15, 162-176, 244-247, 249-253. Plaintiff's allegations regarding Defendant's alleged efforts to prevent competitor drug Synacthen from the U.S. market are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike § 200. Defendant's Notice appears to seek to strike only a portion of § 200, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike § 203. Defendant's Notice appears to seek to strike only a portion of § 203, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike §§ 161 and 175. While Defendant's settlement of legal claims brought by the U.S. Justice Dept. and the FTC are not admissible as evidence of wrongful conduct, the allegations could be relevant as evidence regarding when Plaintiff allegedly learned or was put on notice of Defendant's wrongful conduct.

The Court DENIES Defendant's Motion to Strike §§ 245, 253, 257 and 280. This trial Court does not have the resources to examine each of the 133 referenced statutes from approximately 40 different jurisdictions, which "the Court determines to be subject to a legal bar." The Court notes that it authorized, and Defendant filed, a 25-page moving MPA and a 15-page Reply Brief. The Court will not address issues not properly raised in the substantial briefing.

With respect to Defendants' Request for Judicial Notice ("RJN") Exhs. A-I, the Court GRANTS

judicial notice of the existence of the documents but does not take judicial notice of the truth of the matters stated therein. (See *Licudine v. Cedars-Sinai Med. Ctr.* (2016) 3 Cal.App.5th 881, 902, quoting *In re Joseph H.* (2015) 237 Cal.App.4th 517, 541-542 ("[w]e can take judicial notice of official acts and public records, but we cannot take judicial notice of the truth of the matters stated therein.") The Court GRANTS Defendants' RJN with respect to Exh. J. The Court GRANTS Defendants' RJN with respect to Exhs. K-O only with respect to the non-California legal authorities stated therein; the Court does not take judicial notice of the statements that appear to be legal argument regarding the interpretation of those non-California legal authorities.

The Court GRANTS Plaintiff's RJN with respect to Exh. 1 to the Opp. Weiler Dec. The Court GRANTS Plaintiff's RJN with respect to the existence of Exhs. 2 and 3 to the Opp. Weiler Dec. but does not take judicial notice of the truth of the facts asserted therein.

Dated: 08/19/2020

 Facsimile

Judge Stephen Kaus

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Case Number: RG20056354
Order After Hearing Re: of 08/19/2020

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 08/21/2020.

Chad Finke Executive Officer / Clerk of the Superior Court

By  Digital
Deputy Clerk

EXHIBIT 60

Schneider Wallace Cottrell Konecky
Wotkyns LLP
Attn: Schneider, Todd M.
2000 Powell St.
Suite 1400
Emeryville, CA 94608____

Arnold & Porter Kaye Scholer LLP
Attn: Shapland, Eric D.
777 South Figueroa St.
44th floor
Los Angeles, CA 90017

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Case Management Order

Complaint - Antitrust/Trade Regulation

ORDER re: CASE MANAGEMENT

The Court has ordered the following at the conclusion of a judicially supervised Case Management Conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 11/10/2020 at 03:00 PM in Dept. 19.

Updated Case Management Statements in compliance with Rule of Court 3.725, on Judicial Council Form CM-110, must be filed no later than 10/26/2020. If the foregoing date is a court holiday or a weekend, the time is extended to the next business day.

NOTICES

Clerk is directed to serve endorsed-filed copies of this order, with proof of service, to counsel and to self-represented parties of record by mail.

Any delay in the trial, caused by non-compliance with any order contained herein, shall be the subject of sanctions pursuant to CCP 177.5.

Dated: 08/25/2020

 Facsimile

Judge Stephen Kaus

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

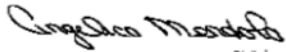
Case Number: RG20056354
Case Management Conference Order of 08/25/2020

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 08/27/2020.

Chad Finke Executive Officer / Clerk of the Superior Court

By  Digital

Deputy Clerk

EXHIBIT 61

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp	No. RG20056354
Plaintiff/Petitioner(s)	
VS.	Minutes
Mallinckrodt ARD LLC	
Defendant/Respondent(s)	
(Abbreviated Title)	

Department 19 Honorable Stephen Kaus, Judge

Cause called for Case Management Conference on August 25, 2020.

Plaintiff Health Care Service Corp represented by Weiler, Matt via bluejeans conference call.
Defendant Mallinckrodt ARD LLC represented by Shapland, Eric D. via bluejeans conference call.
Defendant Mallinckrodt PLC represented by Shapland, Eric D. via bluejeans conference call.

ORDER re: CASE MANAGEMENT

The Court has ordered the following at the conclusion of a judicially supervised Case Management Conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 11/10/2020 at 03:00 PM in Dept. 19.

Updated Case Management Statements in compliance with Rule of Court 3.725, on Judicial Council Form CM-110, must be filed no later than 10/26/2020. If the foregoing date is a court holiday or a weekend, the time is extended to the next business day.

NOTICES

Clerk is directed to serve endorsed-filed copies of this order, with proof of service, to counsel and to self-represented parties of record by mail.

Minutes of 08/25/2020
Entered on 08/26/2020

Chad Finke Executive Officer / Clerk of the Superior Court

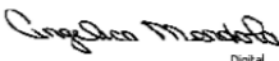
By 
Digital Deputy Clerk

EXHIBIT 62

Schneider Wallace Cottrell Konecky
Wotkyns LLP
Attn: Schneider, Todd M.
2000 Powell St.
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Arnold & Porter Kaye Scholer LLP
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44th floor
Los Angeles, CA 90017

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Case Management Order

Complaint - Antitrust/Trade Regulation

ORDER re: CASE MANAGEMENT

The Court has ordered the following at the conclusion of a judicially supervised Case Management Conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 11/10/2020 at 03:00 PM in Dept. 19.

Updated Case Management Statements in compliance with Rule of Court 3.725, on Judicial Council Form CM-110, must be filed no later than 10/26/2020. If the foregoing date is a court holiday or a weekend, the time is extended to the next business day.

NOTICES

Clerk is directed to serve endorsed-filed copies of this order, with proof of service, to counsel and to self-represented parties of record by mail.

Any delay in the trial, caused by non-compliance with any order contained herein, shall be the subject of sanctions pursuant to CCP 177.5.

Dated: 08/25/2020

 Facsimile

Judge Stephen Kaus

Order

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Case Number: RG20056354
Case Management Conference Order of 08/25/2020

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 08/27/2020.

Chad Finke Executive Officer / Clerk of the Superior Court

By


Digital

Deputy Clerk

EXHIBIT 63

Schneider Wallace Cottrell Konecky
Wotkyns LLP
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Arnold & Porter Kaye Scholer LLP
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44th floor
Los Angeles, CA 90017

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp	No. <u>RG20056354</u>
Plaintiff/Petitioner(s)	Order
VS.	Motion to Strike
Mallinckrodt ARD LLC	Denied
Defendant/Respondent(s)	
(Abbreviated Title)	

The Motion to Strike filed for Mallinckrodt PLC and Mallinckrodt ARD LLC was set for hearing on 08/25/2020 at 09:00 AM in Department 19 before the Honorable Stephen Kaus. The Tentative Ruling was published and was contested.

The matter was argued and submitted, and good cause appearing therefore,

IT IS HEREBY ORDERED THAT:

With respect to defendants Mallinckrodt Ard LLC's and Mallinckrodt plc's (collectively "Defendant") Demurrer to and Motion to Strike Portions of plaintiff Health Care Service Corp.'s ("Plaintiff") Complaint, the Court **SUSTAINS IN PART** and **OVERRULES IN PART** Defendant's Demurrer as set forth below. The Court **DENIES** Defendant's Motion to Strike in its entirety as set forth below.

Plaintiff's Complaint alleges nine Causes of Action based on allegations that it was damaged by Defendants' monopolistic and illegal practices with respect to an adrenocorticotrophic hormone ("ACTH") analogue drug called Acthar, which is used, inter alia, as an anti-inflammatory drug.

FACTS

The Complaint alleges the following relevant facts. Defendant produces H.P. Acthar Gel (Acthar), a drug that was invented in 1948 and first approved by the FDA in 1952. (Complaint ¶¶ 2, 5, 57.) Acthar was approved to treat multiple sclerosis ("MS") in 1979 and to treat infantile spasms in 2010. (Id. ¶¶ 60, 67.) The latter condition is the only one for which Acthar may be considered the most effective "first line" treatment. (Id. at ¶ 67.) Acthar has also been approved for use of idiopathic membranous nephropathy, exacerbations of dermatomyositis (polymyositis), sarcoidosis, and inflammatory eye disease, and as an adjunct therapy to improve effectiveness of primary therapies for psoriatic and rheumatoid arthritis ("RA"). (¶ 64.) As of the filing of the Complaint, Acthar represents 100% of the market for ACTH drugs in the United States. (¶ 183.)

Plaintiff is the nation's largest customer-owned insurer, is an independent licensee of Blue Cross and Blue Shield Association ("BCBSA"), and has an exclusive license to offer BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma and Texas. Plaintiff through its operating divisions and subsidiaries provides Medicare benefits through contracts with the Centers for Medicare and Medicaid Services, provides benefits under various states' Medicaid programs; and private commercial health insurance benefits. Many of the plans operated by Plaintiff offer prescription drug coverage under

which claims for Acthar were submitted and paid by Plaintiff. Plaintiff seeks to recover pursuant to those paid claims. (Id., ¶¶ 17-19.)

Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. (Id. ¶¶ 5, 56.) As a result of the later development of synthetic steroid drugs and non-steroidal anti-inflammatory drugs, by the 1990's only a few key uses, such as for treating infantile spasms, remained for Acthar; and the drug became unprofitable at its then price for then manufacturer Aventis Pharmaceuticals. (¶¶ 6-7.) In 2001, Aventis sold Acthar's rights to Defendant's predecessor Questcor for \$100,000. Questcor raised the price of Acthar from \$40 per unit to \$750 per unit immediately after purchase, to \$1,650 per unit by 2007, at which time the price was raised to \$23,269 per unit. As of 2018, the price had further increased to \$38,892 per unit, such that a single three-unit course of treatment costs nearly \$120,000. (¶¶ 7-8.) Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from just under \$50 million in 2011 to \$636 million in 2016. (¶¶ 72-73.)

Plaintiff alleges that it has paid more than \$100 million for Acthar "during the relevant period," later apparently defined as from 2011 through the present. (¶¶ 85, 200.) Defendant merged with Questcor in August 2014. (¶ 9.)

In June 2007, Defendant "vertically integrated" its sales by distributing Acthar exclusively through the specialty pharmacy CuraScript, "a subsidiary of Express Scripts. CuraScript "is paid a fixed fee for each vial of Acthar" and has the right to return to Defendant any inventory "which goes unsold before its expiration date. (¶¶ 76-84.)

The Complaint alleges that starting in 2010, Defendant established a number of non-profit funds designed to provide assistance to consumers prescribed Acthar to make co-payments required under their health care plans. Defendant set up funds to pay for medications used to treat MS, lupis and RA, which illegally reimbursed co-pays solely for prescriptions of Acthar through 2014. (¶¶ 89-119.) The Complaint alleges on information and belief that Defendant continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 through the present. (¶ 120.)

The Complaint alleges that Defendant began to actively promote off-label uses of Acthar in order to increase sales of the drug. Questcor marketed the drug to focus on "patient types" including those who had had adverse reactions or tolerability problems with IV steroids, even though "common adverse reactions for [Acthar] are similar to those of corticosteroids," which are much less expensive. (¶¶ 121-129.) Questcor's written marketing materials created a false impression that Acthar was better tolerated than steroids. (¶¶ 131-133.) Further, Questcor promoted the so-called "Brod Protocol" requiring a shorter five-day, one vial regimen for Acthar even though there were no peer-reviewed studies showing that Acthar was as effective as less costly alternative drug regimens. Even though this was an admitted off-schedule use of Acthar, Questcor sales representatives routinely told doctors that they should prescribe the five-day regimen and prepared prescription forms with the five-day dosing regimen already written in. (¶¶ 134-145.)

The Complaint further alleges that Defendant paid "kick-backs" to doctors who prescribed Acthar. Defendant did so through a paid speaker program, whereby doctor participants could receive \$2,000 per presentation and up to \$6,000 a day. This was at the high end of industry standard, but a speaking engagement could be to as few as three people who need not be physicians. Approximately, 90% of all Acthar prescriptions are written by approved speakers. Between 2013 and 2016, Defendant paid doctors nearly \$27.5 million in Acthar related payments. (¶¶ 149-156.) A 2018 study published in JAMA Network Open, which appears to use 2015 data, concludes that "aggressive sales tactics and payments from [Defendant] may influence prescribing behavior for [Acthar]." (¶ 158.) Nine doctors who prescribed between \$567,000 and \$3.05 million in Acthar received payments between \$44,000 and \$480,000, although the amounts prescribed by and the amounts paid to each such doctor are not directly proportional. (¶ 159.)

Synacthen is a synthetic ACTH drug approved for sale outside of the United States, where it is used for the same purposes as Acthar. (¶ 162.) In late 2011, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Three other companies engaged in several rounds of negotiations with Novartis with the intent to develop and use Synacthen to compete with Acthar at a lower price. (¶¶ 164-166.) Questcor had "inchoate plans for Synacthen and conducted limited due

diligence when it submitted its initial offer." Yet, Questcor's June 2013 bid, at a minimum of \$135 million, was several multiples higher than the other three bidders, who all submitted comparable offers in terms of value and structure. (§§ 168-169.) However, neither Questcor nor Defendant "made more than superficial efforts to pursue commercialization of Synacthen ... to protect Acthar monopoly pricing." (§ 172.) 14 months after Questcor purchased the rights to Synacthen, Defendant acquired Questcor for \$5.6 billion, an amount almost entirely attributable to the value of Acthar. (§ 171.) In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen in the United States. (§ 176.)

DEMURRER STANDARDS

"A demurrer tests the legal sufficiency of the factual allegations in a complaint." (Redfearn v. Trader Joe's Co. (2018) 20 Cal. App. 5th 989, 996.) "As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are deemed to be true, however improbable they may be," unless the "complaint contains allegations of fact inconsistent with attached documents, or allegations contrary to facts which are judicially noticed." (Del E. Webb Corp. v. Structural Materials Co. (1981) 123 Cal. App. 3d 593, 604.) Courts "construe the complaint 'liberally ... with a view to substantial justice between the parties[.]'" (Goncharov v. Uber Techs., Inc. (2018) 19 Cal. App. 5th 1157, 1165.)

"[I]f a plaintiff pleads a claim that fails to state a cause of action, a demurrer is properly sustained[.]" (Boxer v. City of Beverly Hills (2016) 246 Cal. App. 4th 1212, 1225.) "Where the complaint is defective, ... great liberality should be exercised in permitting a plaintiff to amend [the] complaint." (Redfearn, 20 Cal. App. 5th at 996.) "[L]eave to amend should not be granted where ... amendment would be futile." (Id. at 997.)

ANALYSIS OF DEMURRER

The Complaint alleges nine causes of action: (1) Violation of New Jersey RICO Statute (N.J.S.A. § 2C:41-2(c)); (2) Conspiracy to violate New Jersey RICO (N.J.S.A. § 2C:41-2(d)); (3) Monopolization under State Law, inter alia, Bus. & Prof. ("B&P") Code § 17200 et seq. and CA common law (and for violations of statute for 27 other states and territories); (4) Contract or Conspiracy in Restraint of Trade Under State Laws, inter alia, B&P Code §§ 17200 et seq., 16700 et seq., 16720 et seq., and 16750(a) (and the laws of 30 other states); (5) Unfair and Deceptive Practices under State Laws, inter alia, B&P Code § 17200 et seq. (and the laws of 33 other states); (6) fraud; (7) Insurance Fraud under State Law, inter alia, Cal. Ins. Code § 1871 et seq. (and the laws of 39 other states); (8) Tortious Interference with Contractual Relations; and (9) Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer with respect to the Complaint's Counts 1, 2 (New Jersey RICO violations), 5 (Unfair and Deceptive Practices), 6 (Fraud), 7 (Insurance Fraud), and 9 (Unjust Enrichment). The Court **SUSTAINS WITH LEAVE TO AMEND** Defendant's Demurrer to the Complaint's Counts 3 (Monopolization), 4 (Contract or Conspiracy in Restraint of Trade) and 8 (Tortious Interference with Contractual Relations).

1. Demurrer to Complaint Counts 1 and 2 (New Jersey RICO Violations).

Plaintiff's First two Causes of Actions/Counts are brought under New Jersey's "Little RICO" statute at N.J.S.A. § 2C:41-2(c) and (d). N.J.S.A. § 2C:41-2(c) and (d) provide:

"c. It shall be unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

d. It shall be unlawful for any person to conspire as defined by N.J.S. 2C:5-2, to violate any of the provisions of this section."

§ 2C:5-2 is a statute which defines conspiracy under New Jersey law.

In interpreting New Jersey "Little RICO" statute, it is appropriate to seek guidance from federal decisions construing federal RICO provisions, since New Jersey statute borrows its structure, purpose and remedies from federal legislation. (State v. Ball (1993) 268 N.J.Super. 72, 98, affirmed at 141 N.J.

142; *Maxim Sewerage Corp. v. Monmouth Ridings* (1993) 273 N.J.Super. 84 (although New Jersey RICO statute is broader in application than federal RICO statute, New Jersey will still look to federal case law interpreting RICO to interpret same offense.).)

To state a federal RICO claim, a plaintiff must allege "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." (*Odom v. Microsoft Corp.*, 486 F.3d 541, 547 (9th Cir. 2007) (quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985)). "[T]he conduct must be (5) the proximate cause of harm to the victim." (*Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 997 (9th Cir. 2014).) Racketeering activity "encompass dozens of state and federal offenses, known in RICO parlance as predicates." (*RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2096 (2016).) There is a pattern of racketeering activity where there is "a series of related predicates that together demonstrate the existence or threat of continued criminal activity." (*Id.* at 2096-97.) "[F]ailure to adequately plead a substantive violation of RICO precludes a claim for conspiracy." (*Howard v. Am. Online Inc.*, 208 F.3d 741, 751 (9th Cir. 2000).)

Plaintiff alleges the "Acthar Enterprise," consisting of Defendant, Express Scripts (and its subsidiaries), the Chronic Disease Fund ("CDF"), and the prescribing doctors, was "used as a tool to effectuate a pattern of racketeering activity." (Complaint ¶ 218.) Specifically, Defendant 1) made allegedly false statements, including that Defendant was in compliance with the laws, which constituted mail and wire fraud, as well as use of interstate facilities to conduct unlawful activity, and 2) subsidized co-pays through CDF and made payments to the prescribing doctors which "violated state commercial bribery statutes." (*Id.* ¶¶ 219-227, 149-159.)

In its Demurrer papers, Defendant does not directly attack the allegations of Counts 1 and 2 of Plaintiff's Complaint. Instead, Defendant contends that none the underlying alleged unlawful conduct set forth in the Complaint -- namely (1) Defendant's "vertical integration" of distribution of Acthar, (2) Defendant's use of a charity to fund patient co-pays solely for use of Acthar, (3) Defendant's active, "improper or false" marketing of Acthar for off-label uses, (4) alleged "kickbacks" to doctors who regularly prescribe Acthar, and (5) purchasing the rights to Acthar's only potential competitor Synacthan in order to prevent Synacthen from entering the United States market -- state actionable conduct against Defendant. (See Moving MPA at pp. 17:20-21:28, 24:25-33:18.) Defendant also contends that Plaintiff's claims are time-barred by the applicable statutes of limitations. (*Id.* at pp. 22:1-24:4.)

The Court is not persuaded by either of Defendant's arguments. First, with respect to Defendant's argument that the applicable statutes of limitations have run because Plaintiff had notice of at least some of Defendant's alleged wrongful conduct going back to late 2013 (See Exhs. B-D to Defendant's Request for Judicial Notice in Support of Demurrer and Motion to Strike ("RJN")), the Complaint alleges at ¶¶ 177 and 180 that Defendant actively concealed the existence of its illegal scheme and the acts underlying it through false or misleading statements to Plaintiff and the public and that as a result of this "fraudulent concealment," HCSC could not have discovered and remained unaware of Defendant's wrongful conduct until the Federal Trade Commission and the U.S. Dept. of Justice brought this conduct to light through investigations, legal actions and/or settlements." Further, ¶ 181 alleges continuing injury to Plaintiff. The Court in considering a Demurrer must accept these allegations as true, no matter how unlikely, unless matters of which the Court may take judicial notice refute Plaintiff's allegations as a matter of law.

Although the late 2013 news articles published in *Barron's* and the *New York Times* are evidence tending to show that information regarding Defendant's allegedly improper relationship with CDF was readily available to Plaintiff, they do not as a matter of law establish that Plaintiff had constructive knowledge in 2013 or 2014 of the full extent of Defendant's "racketeering activities" alleged in the Complaint or even that Plaintiff had constructive knowledge of the alleged fraudulent relationship between Defendant and CDF. (See *Richtek USA, Inc. v. uPl Semiconductor Corp.* (2015) 242 Cal.App.4th 651, 660 ("When judicial notice is taken of a document, however, the truthfulness and proper interpretation of the document are disputable."))

Second, the Court finds that Plaintiff has sufficiently alleged a pattern of racketeering activity by Defendant. Plaintiff alleges that Defendant set up a distribution system, which through a subsidiary of Express Scripts, UBC, designed to facilitate and increase sales and prescriptions of Acthar by "interacting directly with patients and third-party payors by coordinating various patient assistance programs, including the ASAP and PAP programs described further below." (¶ 80.) The Complaint

alleges that Defendant set up through CDF co-pay charities the sole purpose of which was to eliminate or substantially reduce (see ¶ 112) co-pays for Acthar to patients, so that patients and their doctors would have no incentive to request alternative, more cost-effective drugs, while leaving insurers like Plaintiff to pay their full portion of the allegedly exorbitant price of Acthar. (¶¶ 89-120.) The Complaint contains numerous, specific factual allegations regarding the degree to which Defendant intentionally and directly worked to connect patients with co-pay assistance funded by Defendant. (Ibid., see particularly ¶¶ 106, 112 alleging that Defendant "implemented an "automatic offering" of co-pay assistance to all patients with co-pays greater than \$150, administered by UBC through [Defendant's] reimbursement hub [ASAP]. The ASAP program referred over 98% of the patients who received subsidies" from three Acthar funds operated by CDF.")

The Complaint further alleges that Defendants actively marketed off-label uses and unapproved dosing regimens to increase demand for Acthar, to make use of Acthar seem more price competitive and also to support misleading representations in marketing materials and by salespersons that Acthar was better tolerated than alternative medications, even though the off-label uses and unapproved dosing regimens were not supported by peer-reviewed studies showing Acthar to be as effective as less-costly alternatives. In fact, the Complaint alleges that Defendant's salespeople pre-filled insurance and prescription forms calling for an unvetted five-day dosing regimen referred to as the "Brod Protocol," so that doctors and other health care providers could more readily prescribe this unapproved dosing regimen. (¶¶ 121-146.)

The Complaint also alleges with respect to payments made by Defendants to doctors that in 2007, Defendant "knew that it might have priced itself out of the MS market;" Defendant "heavily marketed" Acthar to doctors who treated conditions such as MS, RA, and sarcoidosis; "Acthar had not been prescribed in large quantities for these conditions" prior to 2014; in 2014, Defendant's president told investors about "a strategy to expand Acthar's sales to patients" with these and other conditions even though "there were no new medical studies suggesting Acthar was needed to treat any of these conditions;" today, "fewer than 10% of Acthar's sales come from prescriptions for infantile spasms," the main use for which Acthar is a primary treatment; and 88% of doctors who submitted more than 10 claims for Acthar received payment from Defendant, while only 35% of all specialists "receive payments from the pharmaceutical industry." (¶¶ 89, 147-159.)

Finally, the Complaint alleges that Defendant "directly misrepresented to [Plaintiff] that it was complying with state and federal law, including laws related to bribery, kickbacks, and false claims" when Defendant submitted data for Prescription Drug Event (PDE) claims "certifying that such data is true, accurate, and complete." (¶¶ 34-39, 177-178, 200, 259, 267-270.) The Complaint also alleges that Defendant's misrepresentations were part of a fraudulent scheme to increase sales of Acthar and that Plaintiff was damaged thereby. (¶¶ 219, 224, 226-228.)

The Court finds that Counts 1 and 2 of the Complaint adequately state New Jersey RICO violation causes of action. Wherefore, the Court **OVERRULES** Defendant's Demurrer to Counts 1 and 2 of the Complaint.

2. Demurrer to Complaint Counts 5, 6, 7 and 9 for, respectively, State Law Unfair and Deceptive Practices, Fraud, State Law Insurance Fraud, and Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer to the Complaint's Fifth, Sixth, Seventh and Ninth Counts. Defendant's Demurrer MPA does not directly address each of these causes of action. Because the Court has found that Plaintiff has successfully alleged New Jersey "Little RICO" causes of action, the predicates for which involve unfair or deceptive business practices, fraud and insurance fraud, resulting in unjust enrichment to Defendant at Plaintiff's expense, the Court **OVERRULES** the Demurrer to these Counts.

3. Demurrer to Complaint Counts 3 and 4 for, respectively, Monopolization in Violation of State Laws and Contract or Conspiracy in Restraint of Trade in violation of State Law.

The Complaint's Third and Fourth Counts allege solely Defendant's purchase of the U.S. rights to the drug Synacthen from Novartis for the alleged monopolistic purpose of preventing Synacthen from ever competing with Acthar in the United States as the basis for these causes of action. Defendant contends in its MPA that the Complaint fails to allege the relevant Antitrust Market in which Acthar competes and also that the Complaint fails to allege that Plaintiff has been injured as a result of Defendant's

alleged monopolistic actions. (See Moving MPA at pp. 30:1-33:18.)

The Court finds that Defendant's latter argument has more merit than the former. The Complaint alleges facts throughout that undercut Plaintiff's allegation that there is an "ACTH" market of which Acthar is the only current market participant for what Plaintiff has alleged are the off-label uses that now make up the majority of Acthar's sales. (Compare ¶¶ 182-199 with ¶¶ 6, 89, 147-148.) However, ¶¶ 185-186 of the Complaint can be read to identify a small ACTH Market with respect to treatment of infantile spasms and acute exacerbations of MS, for which Synacthen could be the only meaningful competitor to Acthar.

Defendant's argument that the Complaint fails to state facts establishing that Plaintiff has actually suffered damages has greater merit. Based on the facts alleged in the Complaint, Plaintiff is essentially alleging that for a period four years and one month between June 2013 (when Defendant purchased the U.S. rights to Synacthen from Novartis) until July 2017 (when Defendant, as part of a settlement with the FTC, sub-licensed the U.S. rights to Synacthen to West Therapeutic Development, LLC ("West") with the FTC's approval), Defendant wrongfully delayed development of Synacthen as an FDA-approved drug marketable in the U.S. (¶¶ 162-176.) Thus, Plaintiff's alleged damages for Defendant's alleged wrongful conduct can only be the difference between what Plaintiff paid for Acthar and what it would have paid for lower-cost Synacthen during the roughly 4.1 year period when Synacthen would have been on the U.S. market but for Defendant's monopolistic practices.

Moreover, based on the allegations of the Complaint, the only reasonable inference the Court can draw is that since July 2017, West has been working diligently and in good faith to secure FDA approval of Synacthen in the United States. There are also no facts alleged in the Complaint tending to show that, but for Defendant's wrongful conduct, Defendant could have secured FDA approval for Synacthen in a shorter period from its June 2013 purchase date than it will take West to secure FDA approval from West's July 2017 purchase date.

However, the Complaint filed on 2/27/2020 alleges neither that West has already secured FDA approval of Synacthen nor alleged any reasonable estimate regarding when the FDA will approve Synacthen or when Synacthen will actually be available for purchase in the U.S. As such, Plaintiff's claim for damages at present appears to be entirely speculative and hypothetical. For example, if it takes West ten years from purchase to bring Synacthen to the U.S. market, then a finder of fact could reasonably infer that it would have taken Defendant acting in good faith ten years from purchase to bring Synacthen to the U.S. market. If that were the case, Plaintiff would have no damages until the 4.1 year period between June 2023 and July 2027, when but for Defendant's alleged wrongful conduct Plaintiff would have been able to save money by purchasing Synacthen instead of Acthar.

"If the existence-and not the amount-of damages alleged in a fraud pleading is 'too remote, speculative or uncertain,' then the pleading cannot state a claim for relief." (Beckwith v. Dahl (2012) 205 Cal.App.4th 1039, 1064, citing Block v. Tobin (1975) 45 Cal.App.3d 214, 219.) As with fraud claims, "California requires a 'high degree of particularity' in the pleading" antitrust violations. (Freeman v. San Diego Ass'n of Realtors (1999) 77 Cal.App.4th 171, 196.)

In Opposition Plaintiff argues that the federal district court case *Tawfilis v. Allergan, Inc.* (C.D. Cal. 2015) 157 F.Supp.3d 853 supports a finding that Plaintiff has adequately alleged damages based solely on Defendant's alleged wrongful conduct regarding Synacthen. However, *Tawfilis* is distinguishable. While the underlying facts and claims of the dispute in *Tawfilis* are similar to the present action, the *Tawfilis* complaint contained much more detailed allegations than Plaintiff's Complaint does about the steps the potential competitor had taken so that its product Innotox could compete with defendant's Botox in the U.S. market, before the defendant purchased the U.S. rights to Innotox from its potential competitor. The additional alleged facts included the dates on which the competitor applied for and obtained U.S. patents, its plan to build a new manufacturing facility between the first quarter of 2012 and the first quarter of 2013 in order to increase production of Innotox for the entry into the U.S. market, and, most importantly, that Innotox "could have been approved for sale in the U.S. in less than two years following its obtaining regulatory approval abroad in mid-2013." (157 F.Supp.3d at 857.) Based on these allegations, plaintiff *Tawfilis* could allege in his complaint actual damages at least by the time of trial, in light of the 10/20/2015 date on which the federal court's ruling on defendant's Motion to Dismiss entered. In contrast, Plaintiff's Complaint contains no allegations regarding what West has done to obtain FDA approval for Synacthen or when Synacthen might reasonably be available for purchase in the United States.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaints Third and Fourth Counts WITH LEAVE TO AMEND.

4. Demurrer to Complaint Count 8 for Tortious Interference with Contractual Relations.

The Complaint's Eighth Cause of Action appears to be an attempt to allege a cause of action for inducing breach of contract. (See CACI Jury Instruction No. 2200.) The elements of such a cause of action are: (1) the existence of a contract between plaintiff and a third party; (2) that defendant knew of the contract; (3) that defendant's conduct caused the third party to breach the contract; (4) plaintiff was harmed; and (5) defendant's conduct was a substantial factor in causing plaintiff's harm. (Ibid; Pacific Gas & Electric Co. v. Bear Stearns & Co. (1990) 50 Cal.3d 1118,1126.) The Court notes that CACI No. 2021 contains a separate jury instruction for "Intentional Interference with Contractual Relations" where plaintiff must show only that, inter alia, defendant's conduct "made performance [of the third party contract] more expensive or difficult." (PG&E, supra, 50 Cal.3d at 1129.)

As a cause of action for inducing breach of contract, the Eighth Cause of Action fails because this court agrees with the reasoning of the Court in *Humana v. Mallinkrodt Ard LLC* (C.D. Cal. 2020) 2020 WL 3041308 at p. *15, that patients' acceptances of co-pay assistance from a patient assistance program ("PAP"), even if the PAP does not comply with fraud and abuse laws, is not a breach of an insurance agreement that requires members to pay their share of costs for prescription drugs. (See RJN, Exh. A at p. 10.)

In Opposition, Plaintiff contends the 2005 Dept. Health and Human Services Office of Inspector General ("OIG") Bulletin published in the Federal Register relied upon by Defendant and the Humana Court only applies to Medicare Part D beneficiaries and does not apply to non-Medicare Part D beneficiaries who are some of Plaintiff's members. However, this Court considers the OIG guidance evidence of a public policy applicable to all health insurance contracts intended to enable patients with modest incomes to have access to medications, particularly where patients are unlikely to have any personal knowledge whether charity funds like those alleged to have been set up by Defendant do or do not follow legal requirements. Plaintiff specifically alleges that Defendant kept the fraudulent nature of its charities a secret for years. (§§ 177-180.) Where Plaintiff expressly alleges that it, a large and sophisticated player in the health care and medications markets "with more than 16 million members" (§ 17), could not figure out what Defendant was allegedly up to until federal agencies became involved (§ 180), this Court will not impose greater knowledge requirements or duties to investigate on patients.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaint's Count 8 WITH LEAVE TO AMEND. In an amended pleading, Plaintiff may seek to state a cause of action under either of CACI Nos. 2200 or 2201.

MOTION TO STRIKE

MOTION TO STRIKE STANDARDS

"The court may, upon a motion . . . or at any time in its discretion, and upon terms it deems proper: (a) [s]trike out any irrelevant, false, or improper matter inserted in any pleading[;] . . . [and/or] (b) [s]trike out all or any part of any pleading not drawn or filed in conformity with the laws of this state, a court rule, or an order of the court." (CCP § 436.) An "irrelevant matter," or "immaterial allegation," means: (1) an allegation that is not essential to the statement of a claim or defense; (2) an allegation that is neither pertinent to nor supported by an otherwise sufficient claim or defense; or (3) a demand for judgment requesting relief not supported by the allegations of the complaint or cross-complaint. (CCP § 431.10(b).)

ANALYSIS OF DEFENDANT'S MOTION TO STRIKE

The Court DENIES Defendant's Motion to Strike §§ 76-85 regarding Defendant's "vertical integration" of distribution of Acthar. The Court is not persuaded by Plaintiff's arguments that Defendant's actions to limit distribution to a single distributor, Express Scripts, artificially maintained the price of Acthar because it prevented multiple distributors from negotiating to lower prices, because Defendant was still the only producer of Acthar and could thereby set whatever price it wished regardless of the number of distributors in dealt with. Nevertheless, these paragraphs are relevant to the Complaint as a whole

because, for example, they allege that the "integrated services [were] critical to the scheme" (§ 78) because they enabled Defendant to funnel patients using Acthar into Defendant's fraudulent ASAP and PAPs. (§§ 80-84.) Further, § 85 contains allegations relevant to Plaintiff's damages claims.

The Court DENIES Defendant's Motion to Strike §§ 89-120. The Court has found that these paragraphs allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 223 at p. 43:5-6. Defendant does not properly identify the portion § 223 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, while the Court agrees with Defendant and the Humana Court at p. * 13 that co-pay assistance paid by a PAP to patient does not constitute a commercial bribe, the Complaint also alleges Defendant paid "bribes" and "kickbacks" to doctors to prescribe Acthar. N.J.S.A. § 2C:21-10 specifically references a "physician" as a person with a "duty of fidelity" to whom a bribe might be given as consideration for knowing violation of said duty of fidelity.

The Court DENIES Defendant's Motion to Strike §§ 273-275. The Court has found above that the allegations underlying the allegations in these paragraphs are sufficient to allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 281 at p. 56:22. Defendant does not properly identify the portion § 281 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, The Court has found above that the allegations underlying the relevant allegation in these paragraph are sufficient to allege actionable conduct against Defendant.

The Court DENIES Defendant's Motion to Strike §§ 14, 149-161, 259, 272-273. The Court has found above that these allegations are sufficient to state actionable conduct against defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike "§ 181, Ins. 21-22." The Complaint contains no matter meeting this description. (See also CRC Rule 3.1322(a).)

The Court DENIES Defendant's Motion to Strike §§ 13, 121-148. The allegations are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike §§ 15, 162-176, 244-247, 249-253. Plaintiff's allegations regarding Defendant's alleged efforts to prevent competitor drug Synacthen from the U.S. market are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike § 200. Defendant's Notice appears to seek to strike only a portion of § 200, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike § 203. Defendant's Notice appears to seek to strike only a portion of § 203, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike §§ 161 and 175. While Defendant's settlement of legal claims brought by the U.S. Justice Dept. and the FTC are not admissible as evidence of wrongful conduct, the allegations could be relevant as evidence regarding when Plaintiff allegedly learned or was put on notice of Defendant's wrongful conduct.

The Court DENIES Defendant's Motion to Strike §§ 245, 253, 257 and 280. This trial Court does not have the resources to examine each of the 133 referenced statutes from approximately 40 different jurisdictions, which "the Court determines to be subject to a legal bar." The Court notes that it authorized, and Defendant filed, a 25-page moving MPA and a 15-page Reply Brief. The Court will not address issues not properly raised in the substantial briefing.

With respect to Defendants' Request for Judicial Notice ("RJN") Exhs. A-I, the Court GRANTS judicial notice of the existence of the documents but does not take judicial notice of the truth of the matters stated therein. (See *Licudine v. Cedars-Sinai Med. Ctr.* (2016) 3 Cal.App.5th 881, 902, quoting *In re Joseph H.* (2015) 237 Cal.App.4th 517, 541-542 ("[w]e can take judicial notice of official acts and public records, but we cannot take judicial notice of the truth of the matters stated therein.") The Court GRANTS Defendants' RJN with respect to Exh. J. The Court GRANTS Defendants' RJN

with respect to Exhs. K-O only with respect to the non-California legal authorities stated therein; the Court does not take judicial notice of the statements that appear to be legal argument regarding the interpretation of those non-California legal authorities.

The Court GRANTS Plaintiff's RJN with respect to Exh. 1 to the Opp. Weiler Dec. The Court GRANTS Plaintiff's RJN with respect to the existence of Exhs. 2 and 3 to the Opp. Weiler Dec. but does not take judicial notice of the truth of the facts asserted therein.

Dated: 08/26/2020



Judge Stephen Kaus

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Case Number: RG20056354
Order After Hearing Re: of 08/26/2020

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 08/27/2020.

Chad Finke Executive Officer / Clerk of the Superior Court

By


Digital

Deputy Clerk

EXHIBIT 64

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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Order

Demurrer to Complaint
 Sustained

The Demurrer to Complaint filed for Mallinckrodt PLC and Mallinckrodt ARD LLC was set for hearing on 08/25/2020 at 09:00 AM in Department 19 before the Honorable Stephen Kaus. The Tentative Ruling was published and was contested.

The matter was argued and submitted, and good cause appearing therefore,

IT IS HEREBY ORDERED THAT:

With respect to defendants Mallinckrodt Ard LLC's and Mallinckrodt plc's (collectively "Defendant") Demurrer to and Motion to Strike Portions of plaintiff Health Care Service Corp.'s ("Plaintiff") Complaint, the Court SUSTAINS IN PART and OVERRULES IN PART Defendant's Demurrer as set forth below. The Court DENIES Defendant's Motion to Strike in its entirety as set forth below.

Plaintiff's Complaint alleges nine Causes of Action based on allegations that it was damaged by Defendants' monopolistic and illegal practices with respect to an adrenocorticotrophic hormone ("ACTH") analogue drug called Acthar, which is used, inter alia, as an anti-inflammatory drug.

FACTS

The Complaint alleges the following relevant facts. Defendant produces H.P. Acthar Gel (Acthar), a drug that was invented in 1948 and first approved by the FDA in 1952. (Complaint ¶¶ 2, 5, 57.) Acthar was approved to treat multiple sclerosis ("MS") in 1979 and to treat infantile spasms in 2010. (Id. ¶¶ 60, 67.) The latter condition is the only one for which Acthar may be considered the most effective "first line" treatment. (Id. at ¶ 67.) Acthar has also been approved for use of idiopathic membranous nephropathy, exacerbations of dermatomyositis (polymyositis), sarcoidosis, and inflammatory eye disease, and as an adjunct therapy to improve effectiveness of primary therapies for psoriatic and rheumatoid arthritis ("RA"). (¶ 64.) As of the filing of the Complaint, Acthar represents 100% of the market for ACTH drugs in the United States. (¶ 183.)

Plaintiff is the nation's largest customer-owned insurer, is an independent licensee of Blue Cross and Blue Shield Association ("BCBSA"), and has an exclusive license to offer BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma and Texas. Plaintiff through its operating divisions and subsidiaries provides Medicare benefits through contracts with the Centers for Medicare and Medicaid Services, provides benefits under various states' Medicaid programs; and private commercial health insurance benefits. Many of the plans operated by Plaintiff offer prescription drug coverage under

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which claims for Acthar were submitted and paid by Plaintiff. Plaintiff seeks to recover pursuant to those paid claims. (Id., ¶¶ 17-19.)

Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. (Id. ¶¶ 5, 56.) As a result of the later development of synthetic steroid drugs and non-steroidal anti-inflammatory drugs, by the 1990's only a few key uses, such as for treating infantile spasms, remained for Acthar; and the drug became unprofitable at its then price for then manufacturer Aventis Pharmaceuticals. (¶¶ 6-7.) In 2001, Aventis sold Acthar's rights to Defendant's predecessor Questcor for \$100,000. Questcor raised the price of Acthar from \$40 per unit to \$750 per unit immediately after purchase, to \$1,650 per unit by 2007, at which time the price was raised to \$23,269 per unit. As of 2018, the price had further increased to \$38,892 per unit, such that a single three-unit course of treatment costs nearly \$120,000. (¶¶ 7-8.) Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from just under \$50 million in 2011 to \$636 million in 2016. (¶¶ 72-73.)

Plaintiff alleges that it has paid more than \$100 million for Acthar "during the relevant period," later apparently defined as from 2011 through the present. (¶¶ 85, 200.) Defendant merged with Questcor in August 2014. (¶ 9.)

In June 2007, Defendant "vertically integrated" its sales by distributing Acthar exclusively through the specialty pharmacy CuraScript, "a subsidiary of Express Scripts. CuraScript "is paid a fixed fee for each vial of Acthar" and has the right to return to Defendant any inventory "which goes unsold before its expiration date. (¶¶ 76-84.)

The Complaint alleges that starting in 2010, Defendant established a number of non-profit funds designed to provide assistance to consumers prescribed Acthar to make co-payments required under their health care plans. Defendant set up funds to pay for medications used to treat MS, lupis and RA, which illegally reimbursed co-pays solely for prescriptions of Acthar through 2014. (¶¶ 89-119.) The Complaint alleges on information and belief that Defendant continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 through the present. (¶ 120.)

The Complaint alleges that Defendant began to actively promote off-label uses of Acthar in order to increase sales of the drug. Questcor marketed the drug to focus on "patient types" including those who had had adverse reactions or tolerability problems with IV steroids, even though "common adverse reactions for [Acthar] are similar to those of corticosteroids," which are much less expensive. (¶¶ 121-129.) Questcor's written marketing materials created a false impression that Acthar was better tolerated than steroids. (¶¶ 131-133.) Further, Questcor promoted the so-called "Brod Protocol" requiring a shorter five-day, one vial regimen for Acthar even though there were no peer-reviewed studies showing that Acthar was as effective as less costly alternative drug regimens. Even though this was an admitted off-schedule use of Acthar, Questcor sales representatives routinely told doctors that they should prescribe the five-day regimen and prepared prescription forms with the five-day dosing regimen already written in. (¶¶ 134-145.)

The Complaint further alleges that Defendant paid "kick-backs" to doctors who prescribed Acthar. Defendant did so through a paid speaker program, whereby doctor participants could receive \$2,000 per presentation and up to \$6,000 a day. This was at the high end of industry standard, but a speaking engagement could be to as few as three people who need not be physicians. Approximately, 90% of all Acthar prescriptions are written by approved speakers. Between 2013 and 2016, Defendant paid doctors nearly \$27.5 million in Acthar related payments. (¶¶ 149-156.) A 2018 study published in JAMA Network Open, which appears to use 2015 data, concludes that "aggressive sales tactics and payments from [Defendant] may influence prescribing behavior for [Acthar]." (¶ 158.) Nine doctors who prescribed between \$567,000 and \$3.05 million in Acthar received payments between \$44,000 and \$480,000, although the amounts prescribed by and the amounts paid to each such doctor are not directly proportional. (¶ 159.)

Synacthen is a synthetic ACTH drug approved for sale outside of the United States, where it is used for the same purposes as Acthar. (¶ 162.) In late 2011, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Three other companies engaged in several rounds of negotiations with Novartis with the intent to develop and use Synacthen to compete with Acthar at a lower price. (¶¶ 164-166.) Questcor had "inchoate plans for Synacthen and conducted limited due

diligence when it submitted its initial offer." Yet, Questcor's June 2013 bid, at a minimum of \$135 million, was several multiples higher than the other three bidders, who all submitted comparable offers in terms of value and structure. (§§ 168-169.) However, neither Questcor nor Defendant "made more than superficial efforts to pursue commercialization of Synacthen ... to protect Acthar monopoly pricing." (§ 172.) 14 months after Questcor purchased the rights to Synacthen, Defendant acquired Questcor for \$5.6 billion, an amount almost entirely attributable to the value of Acthar. (§ 171.) In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen in the United States. (§ 176.)

DEMURRER STANDARDS

"A demurrer tests the legal sufficiency of the factual allegations in a complaint." (*Redfearn v. Trader Joe's Co.* (2018) 20 Cal. App. 5th 989, 996.) "As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are deemed to be true, however improbable they may be," unless the "complaint contains allegations of fact inconsistent with attached documents, or allegations contrary to facts which are judicially noticed." (*Del E. Webb Corp. v. Structural Materials Co.* (1981) 123 Cal. App. 3d 593, 604.) Courts "construe the complaint 'liberally ... with a view to substantial justice between the parties[.]'" (*Goncharov v. Uber Techs., Inc.* (2018) 19 Cal. App. 5th 1157, 1165.)

"[I]f a plaintiff pleads a claim that fails to state a cause of action, a demurrer is properly sustained[.]" (*Boxer v. City of Beverly Hills* (2016) 246 Cal. App. 4th 1212, 1225.) "Where the complaint is defective, ... great liberality should be exercised in permitting a plaintiff to amend [the] complaint." (*Redfearn*, 20 Cal. App. 5th at 996.) "[L]eave to amend should not be granted where ... amendment would be futile." (*Id.* at 997.)

ANALYSIS OF DEMURRER

The Complaint alleges nine causes of action: (1) Violation of New Jersey RICO Statute (N.J.S.A. § 2C:41-2(c)); (2) Conspiracy to violate New Jersey RICO (N.J.S.A. § 2C:41-2(d)); (3) Monopolization under State Law, inter alia, Bus. & Prof. ("B&P") Code § 17200 et seq. and CA common law (and for violations of statute for 27 other states and territories); (4) Contract or Conspiracy in Restraint of Trade Under State Laws, inter alia, B&P Code §§ 17200 et seq., 16700 et seq., 16720 et seq., and 16750(a) (and the laws of 30 other states); (5) Unfair and Deceptive Practices under State Laws, inter alia, B&P Code § 17200 et seq. (and the laws of 33 other states); (6) fraud; (7) Insurance Fraud under State Law, inter alia, Cal. Ins. Code § 1871 et seq. (and the laws of 39 other states); (8) Tortious Interference with Contractual Relations; and (9) Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer with respect to the Complaint's Counts 1, 2 (New Jersey RICO violations), 5 (Unfair and Deceptive Practices), 6 (Fraud), 7 (Insurance Fraud), and 9 (Unjust Enrichment). The Court **SUSTAINS WITH LEAVE TO AMEND** Defendant's Demurrer to the Complaint's Counts 3 (Monopolization), 4 (Contract or Conspiracy in Restraint of Trade) and 8 (Tortious Interference with Contractual Relations).

1. Demurrer to Complaint Counts 1 and 2 (New Jersey RICO Violations).

Plaintiff's First two Causes of Actions/Counts are brought under New Jersey's "Little RICO" statute at N.J.S.A. § 2C:41-2(c) and (d). N.J.S.A. § 2C:41-2(c) and (d) provide:

"c. It shall be unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

d. It shall be unlawful for any person to conspire as defined by N.J.S. 2C:5-2, to violate any of the provisions of this section."

§ 2C:5-2 is a statute which defines conspiracy under New Jersey law.

In interpreting New Jersey "Little RICO" statute, it is appropriate to seek guidance from federal decisions construing federal RICO provisions, since New Jersey statute borrows its structure, purpose and remedies from federal legislation. (*State v. Ball* (1993) 268 N.J.Super. 72, 98, affirmed at 141 N.J.

142; *Maxim Sewerage Corp. v. Monmouth Ridings* (1993) 273 N.J.Super. 84 (although New Jersey RICO statute is broader in application than federal RICO statute, New Jersey will still look to federal case law interpreting RICO to interpret same offense.).)

To state a federal RICO claim, a plaintiff must allege "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." (*Odom v. Microsoft Corp.*, 486 F.3d 541, 547 (9th Cir. 2007) (quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985)). "[T]he conduct must be (5) the proximate cause of harm to the victim." (*Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 997 (9th Cir. 2014).) Racketeering activity "encompass dozens of state and federal offenses, known in RICO parlance as predicates." (*RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2096 (2016).) There is a pattern of racketeering activity where there is "a series of related predicates that together demonstrate the existence or threat of continued criminal activity." (*Id.* at 2096-97.) "[F]ailure to adequately plead a substantive violation of RICO precludes a claim for conspiracy." (*Howard v. Am. Online Inc.*, 208 F.3d 741, 751 (9th Cir. 2000).)

Plaintiff alleges the "Acthar Enterprise," consisting of Defendant, Express Scripts (and its subsidiaries), the Chronic Disease Fund ("CDF"), and the prescribing doctors, was "used as a tool to effectuate a pattern of racketeering activity." (Complaint ¶ 218.) Specifically, Defendant 1) made allegedly false statements, including that Defendant was in compliance with the laws, which constituted mail and wire fraud, as well as use of interstate facilities to conduct unlawful activity, and 2) subsidized co-pays through CDF and made payments to the prescribing doctors which "violated state commercial bribery statutes." (*Id.* ¶¶ 219-227, 149-159.)

In its Demurrer papers, Defendant does not directly attack the allegations of Counts 1 and 2 of Plaintiff's Complaint. Instead, Defendant contends that none the underlying alleged unlawful conduct set forth in the Complaint -- namely (1) Defendant's "vertical integration" of distribution of Acthar, (2) Defendant's use of a charity to fund patient co-pays solely for use of Acthar, (3) Defendant's active, "improper or false" marketing of Acthar for off-label uses, (4) alleged "kickbacks" to doctors who regularly prescribe Acthar, and (5) purchasing the rights to Acthar's only potential competitor Synacthan in order to prevent Synacthan from entering the United States market -- state actionable conduct against Defendant. (See Moving MPA at pp. 17:20-21:28, 24:25-33:18.) Defendant also contends that Plaintiff's claims are time-barred by the applicable statutes of limitations. (*Id.* at pp. 22:1-24:4.)

The Court is not persuaded by either of Defendant's arguments. First, with respect to Defendant's argument that the applicable statutes of limitations have run because Plaintiff had notice of at least some of Defendant's alleged wrongful conduct going back to late 2013 (See Exhs. B-D to Defendant's Request for Judicial Notice in Support of Demurrer and Motion to Strike ("RJN")), the Complaint alleges at ¶¶ 177 and 180 that Defendant actively concealed the existence of its illegal scheme and the acts underlying it through false or misleading statements to Plaintiff and the public and that as a result of this "fraudulent concealment," HCSC could not have discovered and remained unaware of Defendant's wrongful conduct until the Federal Trade Commission and the U.S. Dept. of Justice brought this conduct to light through investigations, legal actions and/or settlements." Further, ¶ 181 alleges continuing injury to Plaintiff. The Court in considering a Demurrer must accept these allegations as true, no matter how unlikely, unless matters of which the Court may take judicial notice refute Plaintiff's allegations as a matter of law.

Although the late 2013 news articles published in *Barron's* and the *New York Times* are evidence tending to show that information regarding Defendant's allegedly improper relationship with CDF was readily available to Plaintiff, they do not as a matter of law establish that Plaintiff had constructive knowledge in 2013 or 2014 of the full extent of Defendant's "racketeering activities" alleged in the Complaint or even that Plaintiff had constructive knowledge of the alleged fraudulent relationship between Defendant and CDF. (See *Richtek USA, Inc. v. uPI Semiconductor Corp.* (2015) 242 Cal.App.4th 651, 660 ("When judicial notice is taken of a document, however, the truthfulness and proper interpretation of the document are disputable."))

Second, the Court finds that Plaintiff has sufficiently alleged a pattern of racketeering activity by Defendant. Plaintiff alleges that Defendant set up a distribution system, which through a subsidiary of Express Scripts, UBC, designed to facilitate and increase sales and prescriptions of Acthar by "interacting directly with patients and third-party payors by coordinating various patient assistance programs, including the ASAP and PAP programs described further below." (¶ 80.) The Complaint

alleges that Defendant set up through CDF co-pay charities the sole purpose of which was to eliminate or substantially reduce (see ¶ 112) co-pays for Acthar to patients, so that patients and their doctors would have no incentive to request alternative, more cost-effective drugs, while leaving insurers like Plaintiff to pay their full portion of the allegedly exorbitant price of Acthar. (¶¶ 89-120.) The Complaint contains numerous, specific factual allegations regarding the degree to which Defendant intentionally and directly worked to connect patients with co-pay assistance funded by Defendant. (Ibid., see particularly ¶¶ 106, 112 alleging that Defendant "implemented an "automatic offering" of co-pay assistance to all patients with co-pays greater than \$150, administered by UBC through [Defendant's] reimbursement hub [ASAP]. The ASAP program referred over 98% of the patients who received subsidies" from three Acthar funds operated by CDF.")

The Complaint further alleges that Defendants actively marketed off-label uses and unapproved dosing regimens to increase demand for Acthar, to make use of Acthar seem more price competitive and also to support misleading representations in marketing materials and by salespersons that Acthar was better tolerated than alternative medications, even though the off-label uses and unapproved dosing regimens were not supported by peer-reviewed studies showing Acthar to be as effective as less-costly alternatives. In fact, the Complaint alleges that Defendant's salespeople pre-filled insurance and prescription forms calling for an unvetted five-day dosing regimen referred to as the "Brod Protocol," so that doctors and other health care providers could more readily prescribe this unapproved dosing regimen. (¶¶ 121-146.)

The Complaint also alleges with respect to payments made by Defendants to doctors that in 2007, Defendant "knew that it might have priced itself out of the MS market;" Defendant "heavily marketed" Acthar to doctors who treated conditions such as MS, RA, and sarcoidosis; "Acthar had not been prescribed in large quantities for these conditions" prior to 2014; in 2014, Defendant's president told investors about "a strategy to expand Acthar's sales to patients" with these and other conditions even though "there were no new medical studies suggesting Acthar was needed to treat any of these conditions;" today, "fewer than 10% of Acthar's sales come from prescriptions for infantile spasms," the main use for which Acthar is a primary treatment; and 88% of doctors who submitted more than 10 claims for Acthar received payment from Defendant, while only 35% of all specialists "receive payments from the pharmaceutical industry." (¶¶ 89, 147-159.)

Finally, the Complaint alleges that Defendant "directly misrepresented to [Plaintiff] that it was complying with state and federal law, including laws related to bribery, kickbacks, and false claims" when Defendant submitted data for Prescription Drug Event (PDE) claims "certifying that such data is true, accurate, and complete." (¶¶ 34-39, 177-178, 200, 259, 267-270.) The Complaint also alleges that Defendant's misrepresentations were part of a fraudulent scheme to increase sales of Acthar and that Plaintiff was damaged thereby. (¶¶ 219, 224, 226-228.)

The Court finds that Counts 1 and 2 of the Complaint adequately state New Jersey RICO violation causes of action. Wherefore, the Court **OVERRULES** Defendant's Demurrer to Counts 1 and 2 of the Complaint.

2. Demurrer to Complaint Counts 5, 6, 7 and 9 for, respectively, State Law Unfair and Deceptive Practices, Fraud, State Law Insurance Fraud, and Unjust Enrichment.

The Court **OVERRULES** Defendant's Demurrer to the Complaint's Fifth, Sixth, Seventh and Ninth Counts. Defendant's Demurrer MPA does not directly address each of these causes of action. Because the Court has found that Plaintiff has successfully alleged New Jersey "Little RICO" causes of action, the predicates for which involve unfair or deceptive business practices, fraud and insurance fraud, resulting in unjust enrichment to Defendant at Plaintiff's expense, the Court **OVERRULES** the Demurrer to these Counts.

3. Demurrer to Complaint Counts 3 and 4 for, respectively, Monopolization in Violation of State Laws and Contract or Conspiracy in Restraint of Trade in violation of State Law.

The Complaint's Third and Fourth Counts allege solely Defendant's purchase of the U.S. rights to the drug Synacthen from Novartis for the alleged monopolistic purpose of preventing Synacthen from ever competing with Acthar in the United States as the basis for these causes of action. Defendant contends in its MPA that the Complaint fails to allege the relevant Antitrust Market in which Acthar competes and also that the Complaint fails to allege that Plaintiff has been injured as a result of Defendant's

alleged monopolistic actions. (See Moving MPA at pp. 30:1-33:18.)

The Court finds that Defendant's latter argument has more merit than the former. The Complaint alleges facts throughout that undercut Plaintiff's allegation that there is an "ACTH" market of which Acthar is the only current market participant for what Plaintiff has alleged are the off-label uses that now make up the majority of Acthar's sales. (Compare ¶¶ 182-199 with ¶¶ 6, 89, 147-148.) However, ¶¶ 185-186 of the Complaint can be read to identify a small ACTH Market with respect to treatment of infantile spasms and acute exacerbations of MS, for which Synacthen could be the only meaningful competitor to Acthar.

Defendant's argument that the Complaint fails to state facts establishing that Plaintiff has actually suffered damages has greater merit. Based on the facts alleged in the Complaint, Plaintiff is essentially alleging that for a period four years and one month between June 2013 (when Defendant purchased the U.S. rights to Synacthen from Novartis) until July 2017 (when Defendant, as part of a settlement with the FTC, sub-licensed the U.S. rights to Synacthen to West Therapeutic Development, LLC ("West") with the FTC's approval), Defendant wrongfully delayed development of Synacthen as an FDA-approved drug marketable in the U.S. (¶¶ 162-176.) Thus, Plaintiff's alleged damages for Defendant's alleged wrongful conduct can only be the difference between what Plaintiff paid for Acthar and what it would have paid for lower-cost Synacthen during the roughly 4.1 year period when Synacthen would have been on the U.S. market but for Defendant's monopolistic practices.

Moreover, based on the allegations of the Complaint, the only reasonable inference the Court can draw is that since July 2017, West has been working diligently and in good faith to secure FDA approval of Synacthen in the United States. There are also no facts alleged in the Complaint tending to show that, but for Defendant's wrongful conduct, Defendant could have secured FDA approval for Synacthen in a shorter period from its June 2013 purchase date than it will take West to secure FDA approval from West's July 2017 purchase date.

However, the Complaint filed on 2/27/2020 alleges neither that West has already secured FDA approval of Synacthen nor alleged any reasonable estimate regarding when the FDA will approve Synacthen or when Synacthen will actually be available for purchase in the U.S. As such, Plaintiff's claim for damages at present appears to be entirely speculative and hypothetical. For example, if it takes West ten years from purchase to bring Synacthen to the U.S. market, then a finder of fact could reasonably infer that it would have taken Defendant acting in good faith ten years from purchase to bring Synacthen to the U.S. market. If that were the case, Plaintiff would have no damages until the 4.1 year period between June 2023 and July 2027, when but for Defendant's alleged wrongful conduct Plaintiff would have been able to save money by purchasing Synacthen instead of Acthar.

"If the existence-and not the amount-of damages alleged in a fraud pleading is 'too remote, speculative or uncertain,' then the pleading cannot state a claim for relief." (Beckwith v. Dahl (2012) 205 Cal.App.4th 1039, 1064, citing Block v. Tobin (1975) 45 Cal.App.3d 214, 219.) As with fraud claims, "California requires a 'high degree of particularity' in the pleading" antitrust violations. (Freeman v. San Diego Ass'n of Realtors (1999) 77 Cal.App.4th 171, 196.)

In Opposition Plaintiff argues that the federal district court case *Tawfilis v. Allergan, Inc.* (C.D. Cal. 2015) 157 F.Supp.3d 853 supports a finding that Plaintiff has adequately alleged damages based solely on Defendant's alleged wrongful conduct regarding Synacthen. However, *Tawfilis* is distinguishable. While the underlying facts and claims of the dispute in *Tawfilis* are similar to the present action, the *Tawfilis* complaint contained much more detailed allegations than Plaintiff's Complaint does about the steps the potential competitor had taken so that its product Innotox could compete with defendant's Botox in the U.S. market, before the defendant purchased the U.S. rights to Innotox from its potential competitor. The additional alleged facts included the dates on which the competitor applied for and obtained U.S. patents, its plan to build a new manufacturing facility between the first quarter of 2012 and the first quarter of 2013 in order to increase production of Innotox for the entry into the U.S. market, and, most importantly, that Innotox "could have been approved for sale in the U.S. in less than two years following its obtaining regulatory approval abroad in mid-2013." (157 F.Supp.3d at 857.) Based on these allegations, plaintiff *Tawfilis* could allege in his complaint actual damages at least by the time of trial, in light of the 10/20/2015 date on which the federal court's ruling on defendant's Motion to Dismiss entered. In contrast, Plaintiff's Complaint contains no allegations regarding what West has done to obtain FDA approval for Synacthen or when Synacthen might reasonably be available for purchase in the United States.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaints Third and Fourth Counts WITH LEAVE TO AMEND.

4. Demurrer to Complaint Count 8 for Tortious Interference with Contractual Relations.

The Complaint's Eighth Cause of Action appears to be an attempt to allege a cause of action for inducing breach of contract. (See CACI Jury Instruction No. 2200.) The elements of such a cause of action are: (1) the existence of a contract between plaintiff and a third party; (2) that defendant knew of the contract; (3) that defendant's conduct caused the third party to breach the contract; (4) plaintiff was harmed; and (5) defendant's conduct was a substantial factor in causing plaintiff's harm. (Ibid; Pacific Gas & Electric Co. v. Bear Stearns & Co. (1990) 50 Cal.3d 1118,1126.) The Court notes that CACI No. 2021 contains a separate jury instruction for "Intentional Interference with Contractual Relations" where plaintiff must show only that, inter alia, defendant's conduct "made performance [of the third party contract] more expensive or difficult." (PG&E, supra, 50 Cal.3d at 1129.)

As a cause of action for inducing breach of contract, the Eighth Cause of Action fails because this court agrees with the reasoning of the Court in Humana v. Mallinkrodt Ard LLC (C.D. Cal. 2020) 2020 WL 3041308 at p. *15, that patients' acceptances of co-pay assistance from a patient assistance program ("PAP"), even if the PAP does not comply with fraud and abuse laws, is not a breach of an insurance agreement that requires members to pay their share of costs for prescription drugs. (See RJN, Exh. A at p. 10.)

In Opposition, Plaintiff contends the 2005 Dept. Health and Human Services Office of Inspector General ("OIG") Bulletin published in the Federal Register relied upon by Defendant and the Humana Court only applies to Medicare Part D beneficiaries and does not apply to non-Medicare Part D beneficiaries who are some of Plaintiff's members. However, this Court considers the OIG guidance evidence of a public policy applicable to all health insurance contracts intended to enable patients with modest incomes to have access to medications, particularly where patients are unlikely to have any personal knowledge whether charity funds like those alleged to have been set up by Defendant do or do not follow legal requirements. Plaintiff specifically alleges that Defendant kept the fraudulent nature of its charities a secret for years. (§§ 177-180.) Where Plaintiff expressly alleges that it, a large and sophisticated player in the health care and medications markets "with more than 16 million members" (§ 17), could not figure out what Defendant was allegedly up to until federal agencies became involved (§ 180), this Court will not impose greater knowledge requirements or duties to investigate on patients.

Wherefore, the Court SUSTAINS Defendant's Demurrer to the Complaint's Count 8 WITH LEAVE TO AMEND. In an amended pleading, Plaintiff may seek to state a cause of action under either of CACI Nos. 2200 or 2201.

MOTION TO STRIKE

MOTION TO STRIKE STANDARDS

"The court may, upon a motion . . . or at any time in its discretion, and upon terms it deems proper: (a) [s]trike out any irrelevant, false, or improper matter inserted in any pleading[;] . . . [and/or] (b) [s]trike out all or any part of any pleading not drawn or filed in conformity with the laws of this state, a court rule, or an order of the court." (CCP § 436.) An "irrelevant matter," or "immaterial allegation," means: (1) an allegation that is not essential to the statement of a claim or defense; (2) an allegation that is neither pertinent to nor supported by an otherwise sufficient claim or defense; or (3) a demand for judgment requesting relief not supported by the allegations of the complaint or cross-complaint. (CCP § 431.10(b).)

ANALYSIS OF DEFENDANT'S MOTION TO STRIKE

The Court DENIES Defendant's Motion to Strike §§ 76-85 regarding Defendant's "vertical integration" of distribution of Acthar. The Court is not persuaded by Plaintiff's arguments that Defendant's actions to limit distribution to a single distributor, Express Scripts, artificially maintained the price of Acthar because it prevented multiple distributors from negotiating to lower prices, because Defendant was still the only producer of Acthar and could thereby set whatever price it wished regardless of the number of distributors in dealt with. Nevertheless, these paragraphs are relevant to the Complaint as a whole

because, for example, they allege that the "integrated services [were] critical to the scheme" (§ 78) because they enabled Defendant to funnel patients using Acthar into Defendant's fraudulent ASAP and PAPs. (§§ 80-84.) Further, § 85 contains allegations relevant to Plaintiff's damages claims.

The Court DENIES Defendant's Motion to Strike §§ 89-120. The Court has found that these paragraphs allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 223 at p. 43:5-6. Defendant does not properly identify the portion § 223 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, while the Court agrees with Defendant and the Humana Court at p. * 13 that co-pay assistance paid by a PAP to patient does not constitute a commercial bribe, the Complaint also alleges Defendant paid "bribes" and "kickbacks" to doctors to prescribe Acthar. N.J.S.A. § 2C:21-10 specifically references a "physician" as a person with a "duty of fidelity" to whom a bribe might be given as consideration for knowing violation of said duty of fidelity.

The Court DENIES Defendant's Motion to Strike §§ 273-275. The Court has found above that the allegations underlying the allegations in these paragraphs are sufficient to allege actionable conduct against Defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike § 281 at p. 56:22. Defendant does not properly identify the portion § 281 to be stricken "verbatim" in violation of CRC Rule 3.1322(a). Further, The Court has found above that the allegations underlying the relevant allegation in these paragraph are sufficient to allege actionable conduct against Defendant.

The Court DENIES Defendant's Motion to Strike §§ 14, 149-161, 259, 272-273. The Court has found above that these allegations are sufficient to state actionable conduct against defendant for pleading purposes.

The Court DENIES Defendant's Motion to Strike "§ 181, Ins. 21-22." The Complaint contains no matter meeting this description. (See also CRC Rule 3.1322(a).)

The Court DENIES Defendant's Motion to Strike §§ 13, 121-148. The allegations are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike §§ 15, 162-176, 244-247, 249-253. Plaintiff's allegations regarding Defendant's alleged efforts to prevent competitor drug Synacthen from the U.S. market are relevant to Plaintiff's allegations of Defendant's illegal scheme.

The Court DENIES Defendant's Motion to Strike § 200. Defendant's Notice appears to seek to strike only a portion of § 200, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike § 203. Defendant's Notice appears to seek to strike only a portion of § 203, but Defendant has not complied with CRC Rule 3.1322(a).

The Court DENIES Defendant's Motion to Strike §§ 161 and 175. While Defendant's settlement of legal claims brought by the U.S. Justice Dept. and the FTC are not admissible as evidence of wrongful conduct, the allegations could be relevant as evidence regarding when Plaintiff allegedly learned or was put on notice of Defendant's wrongful conduct.

The Court DENIES Defendant's Motion to Strike §§ 245, 253, 257 and 280. This trial Court does not have the resources to examine each of the 133 referenced statutes from approximately 40 different jurisdictions, which "the Court determines to be subject to a legal bar." The Court notes that it authorized, and Defendant filed, a 25-page moving MPA and a 15-page Reply Brief. The Court will not address issues not properly raised in the substantial briefing.

With respect to Defendants' Request for Judicial Notice ("RJN") Exhs. A-I, the Court GRANTS judicial notice of the existence of the documents but does not take judicial notice of the truth of the matters stated therein. (See *Licudine v. Cedars-Sinai Med. Ctr.* (2016) 3 Cal.App.5th 881, 902, quoting *In re Joseph H.* (2015) 237 Cal.App.4th 517, 541-542 ("[w]e can take judicial notice of official acts and public records, but we cannot take judicial notice of the truth of the matters stated therein.") The Court GRANTS Defendants' RJN with respect to Exh. J. The Court GRANTS Defendants' RJN

with respect to Exhs. K-O only with respect to the non-California legal authorities stated therein; the Court does not take judicial notice of the statements that appear to be legal argument regarding the interpretation of those non-California legal authorities.

The Court GRANTS Plaintiff's RJN with respect to Exh. 1 to the Opp. Weiler Dec. The Court GRANTS Plaintiff's RJN with respect to the existence of Exhs. 2 and 3 to the Opp. Weiler Dec. but does not take judicial notice of the truth of the facts asserted therein.

Dated: 08/26/2020



Judge Stephen Kaus

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Case Number: RG20056354
Order After Hearing Re: of 08/26/2020

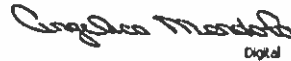
DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 08/27/2020.

Chad Finke Executive Officer / Clerk of the Superior Court

By


Digital

Deputy Clerk

EXHIBIT 65

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Attorneys for Plaintiff

Health Care Service Corporation

[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**STIPULATION TO AMEND
BRIEFING SCHEDULE AND
[PROPOSED] ORDER**

Dept: 19
Judge: Hon. Stephen Kaus

Action Filed: February 27, 2020

1 **WHEREAS**, Plaintiff Health Care Service Corp. (“HCSC”) filed its Complaint in this
 2 action on February 27, 2020 and personally served the Summons and Complaint on Defendants
 3 Mallinckrodt ARD, LLC and Mallinckrodt plc (collectively “Mallinckrodt”) on March 5, 2020.

4 **WHEREAS**, this case has been assigned to Department 19 and the Hon. Stephen Kaus.

5 **WHEREAS**, on August 26, 2020 the Court entered an order sustaining in part and
 6 overruling in part Defendants’ demurrer to HCSC’s Complaint with leave to amend.

7 **WHEREAS**, HCSC wishes to amend its Complaint;

8 **WHEREAS**, the Court has set a Case Management Conference on November 10, 2020 at
 9 3 PM in Department 19;

10 **WHEREAS**, HCSC and Mallinckrodt have conferred about a schedule for HCSC to
 11 amend its Complaint and for Mallinckrodt to file any responsive motion;

12 **NOW THEREFORE**, the parties submit this Stipulation and [Proposed] Order and
 13 request the Court’s consent to the briefing scheduled proposed herein. HCSC and Mallinckrodt
 14 agree that (1) HCSC should have up until October 1, 2020 to file an amended Complaint; (2)
 15 Mallinckrodt should have until October 30, 2020 to file an demurrer or answer; (3) HCSC should
 16 have until November 16, 2020 to file an opposition to any demurrer; (4) Mallinckrodt should have
 17 until November 30, 2020 to file a reply in support of any demurrer. Mallinckrodt shall reserve a
 18 hearing on any motion in Department 19 in December 2020 or January 2021 at the Court’s
 19 convenience.

20 **IT IS SO STIPULATED.**

21
 22
 23 Dated: September 14, 2020

By: /s/ Matthew S. Weiler
 Todd M. Schneider (SBN 158253)
 Jason H. Kim (SBN 220279)
 Matthew S. Weiler (SBN 236052)
 Kyle G. Bates (SBN 299114)
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*Counsel for Plaintiff Health Care Service
Corporation*

Dated: September 8, 2020

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adam.pergament@arnoldporter.com

*Attorneys for Defendants
Mallinckrodt ARD LLC and
Mallinckrodt plc*

IT IS SO ORDERED:

Dated: _____

By: _____
HON. STEPHEN KAUS
JUDGE OF THE SUPERIOR COURT
FOR THE COUNTY OF ALAMEDA

EXHIBIT 66

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Jason H. Kim (SBN 220279)
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[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

Hon. Stephen Kaus

PROOF OF SERVICE

PROOF OF SERVICE

I, Kelle J. Winter, declare the following:

I am over the age of eighteen years and not a party to the within entitled action. I am employed at Schneider Wallace Cottrell Konecky LLP located at 2000 Powell Street, Suite 1400, Emeryville, CA 94608.

On **September 14, 2020**, I served the following document(s) described as:

- **STIPULATION TO AMEND BRIEFING SCHEDULE AND [PROPOSED] ORDER**

on the following interested party(s):

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adam.pergament@arnoldporter

*Attorneys for Defendants
Mallinckrodt ARD LLC and
Mallinckrodt plc*

☒ **BY ELECTRONIC SERVICE** by electronically mailing a true and correct copy in PDF format through SWCKW's electronic mail system to the email address(s) set forth above.

1 I declare under penalty of perjury under the laws of the State of California that the foregoing is
2 true and correct. Executed on September 14, 2020, at Scottsdale, Arizona.

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5 /s/ Kelle J. Winter
6 Kelle J. Winter
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EXHIBIT 67

SCHNEIDER WALLACE COTTRELL KONECKY LLP

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Attorneys for Plaintiff

Health Care Service Corporation

[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

STIPULATION TO AMEND
BRIEFING SCHEDULE AND
~~PROPOSED~~ ORDER

Dept: 19
Judge: Hon. Stephen Kaus

Action Filed: February 27, 2020

(note 11/10/20 CMC continued
to 2/2/2021)

STIPULATION AND ~~PROPOSED~~ ORDER RE BRIEFING SCHEDULE

1 **WHEREAS**, Plaintiff Health Care Service Corp. ("HCSC") filed its Complaint in this
 2 action on February 27, 2020 and personally served the Summons and Complaint on Defendants
 3 Mallinckrodt ARD, LLC and Mallinckrodt plc (collectively "Mallinckrodt") on March 5, 2020.

4 **WHEREAS**, this case has been assigned to Department 19 and the Hon. Stephen Kaus.

5 **WHEREAS**, on August 26, 2020 the Court entered an order sustaining in part and
 6 overruling in part Defendants' demurrer to HCSC's Complaint with leave to amend.

7 **WHEREAS**, HCSC wishes to amend its Complaint;

8 **WHEREAS**, the Court has set a Case Management Conference on November 10, 2020 at
 9 3 PM in Department 19;

10 **WHEREAS**, HCSC and Mallinckrodt have conferred about a schedule for HCSC to
 11 amend its Complaint and for Mallinckrodt to file any responsive motion;

12 **NOW THEREFORE**, the parties submit this Stipulation and [Proposed] Order and
 13 request the Court's consent to the briefing scheduled proposed herein. HCSC and Mallinckrodt
 14 agree that (1) HCSC should have up until October 1, 2020 to file an amended Complaint; (2)
 15 Mallinckrodt should have until October 30, 2020 to file an demurrer or answer; (3) HCSC should
 16 have until November 16, 2020 to file an opposition to any demurrer; (4) Mallinckrodt should have
 17 until November 30, 2020 to file a reply in support of any demurrer. Mallinckrodt shall reserve a
 18 hearing on any motion in Department 19 in December 2020 or January 2021 at the Court's
 19 convenience.

20 **IT IS SO STIPULATED.**

*The 11/10/20 case management
 is continued to 2/2/2021
 3 p.m. Dept 19.*

21
 22
 23 Dated: September 14, 2020

By: /s/ Matthew S. Weiler

Todd M. Schneider (SBN 158253)

Jason H. Kim (SBN 220279)

Matthew S. Weiler (SBN 236052)

Kyle G. Bates (SBN 299114)

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*Counsel for Plaintiff Health Care Service
 Corporation*

Dated: September 8, 2020

By: /s/ D. Eric Shapland (by permission)
 D. Eric Shapland


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3 michael.b.bernstein@arnoldporter.com
4 adam.pergament@arnoldporter.com

5 *Attorneys for Defendants*
6 *Mallinckrodt ARD LLC and*
7 *Mallinckrodt plc*

8 **IT IS SO ORDERED:**
9 Dated: 8/15/2020

By: 
10 HON. STEPHEN KAUS
11 JUDGE OF THE SUPERIOR COURT
12 FOR THE COUNTY OF ALAMEDA
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SUPERIOR COURT OF CALIFORNIA
COUNTY OF ALAMEDA

Case Number: RG20056354

Case Name: HEALTH CARE SERVICE CORP v. MALLINCKRODT ARD LLC

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy **Order Granting Stipulation To Amend Briefing Schedule** filed on September 17, 2020 was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1221 Oak Street, Oakland, California.

I declare under penalty of perjury that the foregoing is true and correct. Executed on September 18, 2020.

Chad Finke, Executive Officer/Clerk of the Superior Court

By: _____



Angelica Mendola
Deputy Clerk

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EXHIBIT 68

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Attorneys for Plaintiffs

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiffs,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendant.

Case No. RG20056354

PROOF OF SERVICE

PROOF OF SERVICE

I, Kelle J. Winter, declare the following:

I am over the age of eighteen years and not a party to the within entitled action. I am employed at Schneider Wallace Cottrell Konecky LLP located at 2000 Powell Street, Suite 1400, Emeryville, CA 94608.

On **October 1, 2020**, I served the following document(s) described as:

- **FIRST AMENDED COMPLAINT**

on the following interested party(s):

D. Eric Shapland
ARNOLD & PORTER KAYE SCHOLER LLP
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eric.shapland@arnoldporter.com

☒ **BY ELECTRONIC SERVICE** by electronically mailing a true and correct copy in PDF format through SWCK's electronic mail system to the email address(s) set forth above.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on October 1, 2020, at Scottsdale, Arizona.

/s/ Kelle J. Winter
Kelle J. Winter